§ 870.3605 Pacing system analyzer.

(a) Identification. A pacing system analyzer (PSA) is a prescription device that combines the functionality of a pacemaker electrode function tester (§ 870.3720) and an external pacemaker pulse generator (EPPG) (§ 870.3600). It is connected to a pacemaker lead and uses a power supply and electronic circuits to supply an accurately calibrated, variable pacing pulse for measuring the patient’s pacing threshold and intracardiac R-wave potential. A PSA may be a single, dual, or triple chamber system and can simultaneously deliver pacing therapy while testing one or more implanted pacing leads.

(b) Classification. Class II (special controls). The special controls for this device are:

(1) Appropriate analysis/testing must validate electromagnetic compatibility (EMC) within a hospital environment.

(2) Electrical bench testing must demonstrate device safety during intended use. This must include testing with the specific power source (i.e., battery power, AC mains connections, or both).

(3) Non-clinical performance testing data must demonstrate the performance characteristics of the device. Testing must include the following:

(i) Testing must demonstrate the accuracy of monitoring functions, alarms, measurement features, therapeutic features, and all adjustable or programmable parameters as identified in labeling;

(ii) Mechanical bench testing of material strength must demonstrate that the device and connection cables will withstand forces or conditions encountered during use;

(iii) Simulated use analysis/testing must demonstrate adequate user interface for adjustable parameters, performance of alarms, display screens, interface with external devices (e.g., data storage, printing), and indicator(s) functionality under intended use conditions; and

(iv) Methods and instructions for cleaning the pulse generator and connection cables must be validated.

(4) Appropriate software verification, validation, and hazard analysis must be performed.

(5) Labeling must include the following:

(i) The labeling must clearly state that these devices are intended for use in a hospital environment and under the supervision of a clinician trained in their use;

(ii) Connector terminals should be clearly, unambiguously marked on the outside of the PSA. The markings should identify positive (+) and negative (−) polarities. Dual chamber devices should clearly identify atrial and ventricular terminals;

(iii) The labeling must list all pacing modes available in the device;

(iv) Labeling must include a detailed description of any special capabilities (e.g., overdrive pacing or automatic mode switching); and

(v) Appropriate electromagnetic compatibility information must be included.

3. In Subpart D, add § 870.3605 to read as follows:

§ 870.3605 Pacing system analyzer.

(a) Identification. A pacing system analyzer (PSA) is a prescription device that combines the functionality of a pacemaker electrode function tester (§ 870.3720) and an external pacemaker pulse generator (EPPG) (§ 870.3600). It is connected to a pacemaker lead and uses a power supply and electronic circuits to supply an accurately calibrated, variable pacing pulse for measuring the patient’s pacing threshold and intracardiac R-wave potential. A PSA may be a single, dual, or triple chamber system and can simultaneously deliver pacing therapy while testing one or more implanted pacing leads.

(b) Classification. Class II (special controls). The special controls for this device are:

(1) Appropriate analysis/testing must validate electromagnetic compatibility (EMC) within a hospital environment.

(2) Electrical bench testing must demonstrate device safety during intended use. This must include testing with the specific power source (i.e., battery power, AC mains connections, or both).

(3) Non-clinical performance testing data must demonstrate the performance characteristics of the device. Testing must include the following:

(i) Testing must demonstrate the accuracy of monitoring functions, alarms, measurement features, therapeutic features, and all adjustable or programmable parameters as identified in labeling;

(ii) Mechanical bench testing of material strength must demonstrate that the device and connection cables will withstand forces or conditions encountered during use;

(iii) Simulated use analysis/testing must demonstrate adequate user interface for adjustable parameters, performance of alarms, display screens, interface with external devices (e.g., data storage, printing), and indicator(s) functionality under intended use conditions; and

(iv) Methods and instructions for cleaning the pulse generator and connection cables must be validated.

(4) Appropriate software verification, validation, and hazard analysis must be performed.

(5) Labeling must include the following:

(i) The labeling must clearly state that these devices are intended for use in a hospital environment and under the supervision of a clinician trained in their use;

(ii) Connector terminals should be clearly, unambiguously marked on the outside of the PSA. The markings should identify positive (+) and negative (−) polarities. Dual chamber devices should clearly identify atrial and ventricular terminals. Triple chamber devices should clearly identify atrial, right ventricular, and left ventricular terminals;

(iii) The labeling must list all pacing modes available in the device;

(iv) Labeling must include a detailed description of any special capabilities (e.g., overdrive pacing or automatic mode switching);

(v) Labeling must limit the use of external pacing to the implant procedure; and

(vi) Appropriate electromagnetic compatibility information must be included.

Dated: April 12, 2016.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2016–08898 Filed 4–15–16; 8:45 am]

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DEPARTMENT OF LABOR
Occupational Safety and Health Administration

29 CFR Part 1987

[DOcket Number: OSHA–2011–0859]

RIN 1218–AC58

Procedures for Handling Retaliation Complaints Under Section 402 of the FDA Food Safety Modernization Act

AGENCY: Occupational Safety and Health Administration, Labor.

ACTION: Final rule.

SUMMARY: This document provides the final text of regulations governing the employee protection (retaliation or whistleblower) provision found at section 402 of the FDA Food Safety Modernization Act (FSMA), which added section 1012 to the Federal Food, Drug, and Cosmetic Act. An interim final rule governing these provisions and requesting public comment was published in the Federal Register on February 13, 2014. Two comments were received that were responsive to the rule. This rule responds to those comments and establishes the final procedures and time frames for the handling of retaliation complaints under FSMA, including procedures and time frames for employee complaints to the Occupational Safety and Health Administration (OSHA), investigations by OSHA, appeals of OSHA determinations to an administrative law judge (ALJ) for a hearing de novo, hearings by ALJs, review of ALJ decisions by the Administrative Review Board (ARB) (acting on behalf of the Secretary of Labor), and judicial review of the Secretary’s final decision.

DATES: This final rule is effective on April 18, 2016.

FOR FURTHER INFORMATION CONTACT: Cleveland Fairchild, Program Analyst, Directorate of Whistleblower Protection Programs, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–4618, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2199. This is not a toll-free number. Email: OSHA.DWPP@dol.gov. This Federal Register publication is available in alternative formats. The alternative formats available are: Large print, electronic file on computer disk (Word Perfect, ASCII, Mates with Duxbury Braille System), and audiotape.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Food Safety Modernization Act (Pub. L. 111–153, 124 Stat. 3885), was signed into law on January 4, 2011. Section 402 of the FDA Food Safety Modernization Act amended the Federal Food, Drug, and Cosmetic Act (FD&C) to add section 1012, 21 U.S.C. 399d, which provides protection to employees against retaliation by an entity engaged in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food for engaging in certain protected activities. Section 1012 protects employees against retaliation because they provided or are about to provide to their employer, the
Federal Government, or the attorney general of a State information relating to any violation of, or any act or omission the employee reasonably believes to be a violation of, any provision of the FD&C or any order, rule, regulation, standard, or ban under the FD&C; testified or are about to testify in a proceeding concerning such violation; assisted or participated, or are about to assist or participate, in such a proceeding; or objected to, or refused to participate in, any activity, policy, practice, or assigned task that the employee reasonably believed to be in violation of any provision of the FD&C or any order, rule, regulation, standard, or ban under the FD&C.

Section 1012 became effective upon enactment on January 4, 2011. Although the Food and Drug Administration of the U.S. Department of Health and Human Services (FDA) generally administers the FD&C, the Secretary of Labor is responsible for enforcing the employee protection provision set forth in section 1012 of the FD&C. These rules establish procedures for the handling of whistleblower complaints under section 1012 of the FD&C. Throughout this rule, FSMA refers to section 402 of the FDA Food Safety Modernization Act, codified as section 1012 of the Federal Food, Drug and Cosmetic Act. See 21 U.S.C. 399d.

II. Summary of Statutory Procedures

FSMA’s whistleblower provisions include procedures that allow a covered employee to file, within 180 days of the alleged retaliation, a complaint with the Secretary of Labor (Secretary). Upon receipt of the complaint, the Secretary must provide written notice to the person or persons named in the complaint alleged to have violated the FSMA (respondent) of the filing of the complaint, the allegations contained in the complaint, the substance of the evidence supporting the complaint, and the rights afforded the respondent throughout the investigation. The Secretary must then, within 60 days of receipt of the complaint, afford the complainant and respondent an opportunity to submit a response and meet with the investigator to present statements from witnesses, and conduct an investigation.

The statute provides that the Secretary may conduct an investigation only if the complainant has made a prima facie showing that the protected activity was a contributing factor in the adverse action alleged in the complaint and the respondent has not demonstrated, through clear and convincing evidence, that it would have taken the same adverse action in the absence of that activity (see section 1987.104 for a summary of the investigation process). OSHA interprets the prima facie case requirement as allowing the complainant to meet this burden through the complaint as supplemented by interviews of the complainant.

After investigating a complaint, the Secretary will issue written findings. If, as a result of the investigation, the Secretary finds there is reasonable cause to believe that retaliation has occurred, the Secretary must notify the respondent of those findings, along with a preliminary order that requires the respondent to, where appropriate: Take affirmative action to abate the violation; reinstate the complainant to his or her former position together with the compensation of that position (including back pay) and restore the terms, conditions, and privileges associated with his or her employment; and provide compensatory damages to the complainant, as well as all costs and expenses (including attorney fees and expert witness fees) reasonably incurred by the complainant for, or in connection with, the bringing of the complaint upon which the order was issued.

The complainant and the respondent then have 30 days after the date of the Secretary’s notification in which to file objections to the findings and/or preliminary order and request a hearing before an administrative law judge (ALJ) at the Department of Labor. The filing of objections under FSMA will stay any remedy in the preliminary order except for preliminary reinstatement. If a hearing before an ALJ is not requested within 30 days, the preliminary order becomes final and is not subject to judicial review.

If a hearing is held, the statute requires the hearing to be conducted “expeditiously.” The Secretary then has 120 days after the conclusion of any hearing in which to issue a final order, which may provide appropriate relief or deny the complaint. Until the Secretary’s final order is issued, the Secretary, the complainant, and the respondent may enter into a settlement agreement that terminates the proceeding. Where the Secretary has determined that a violation has occurred, the Secretary, where appropriate, will assess against the respondent a sum equal to the total amount of all costs and expenses, including attorney and expert witness fees, reasonably incurred by the complainant for, or in connection with, the bringing of the complaint upon which the Secretary issued the order. The Secretary also may award a prevailing employer reasonable attorney fees, not exceeding $1,000, if the Secretary finds that the complaint is frivolous or has been brought in bad faith.

Within 60 days of the issuance of the final order, any person adversely affected or aggrieved by the Secretary’s final order may file an appeal with the United States Court of Appeals for the circuit in which the violation allegedly occurred or the circuit where the complainant resided on the date of the violation.

FSMA permits the employee to seek de novo review of the complaint by a United States district court in the event that the Secretary has not issued a final decision within 210 days after the filing of the complaint, or within 90 days after receiving a written determination. The court will have jurisdiction over the action without regard to the amount in controversy, and the case will be tried before a jury at the request of either party.

FSMA also provides that nothing therein preempts or diminishes any other safeguards against discrimination, demotion, discharge, suspension, threats, harassment, reprisal, retaliation, or any other manner of discrimination provided by Federal or State law. Finally, FSMA states that nothing therein shall be deemed to diminish the rights, privileges, or remedies of any employee under any Federal or State law or under any collective bargaining agreement, and the rights and remedies in FSMA may not be waived by any agreement, policy, form, or condition of employment.

III. Summary and Discussion of Regulatory Provisions

On February 13, 2014, OSHA published in the Federal Register an interim final rule (IFR) establishing rules governing the whistleblower provisions of 402 of the FDA Food Safety Modernization Act. 79 FR 8619. OSHA provided the public an opportunity to comment on the IFR by April 14, 2014. In response, OSHA received comments that were responsive to the rule from two organizations. Comments were received from the Roll Law Group (Roll), on behalf of Paramount Farming Company LLC, Paramount Farms International LLC, Pom Wonderful LLC, and Paramount Citrus Holdings LLC, and; Kalijarvi, Chuzi, Newman & Fitch, P.C. (Kalijarvi). OSHA also received one comment that was not responsive to the rule.

OSHA has reviewed and considered the comments and now adopts this final rule with minor revisions. The following discussion addresses the
on this section, and no changes were made to it.

Section 1987.101 Definitions

This section includes general definitions from the FD&C, which are applicable to the whistleblower provisions of FSMA. The FD&C states that the term “person” includes an individual, partnership, corporation, and association. See 21 U.S.C. 321(e). The FD&C also defines the term “food” as “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.” See 21 U.S.C. 321(f).

No comments were received on this section, and no changes were made to it.

Section 1987.102 Obligations and Prohibited Acts

This section describes the activities that are protected under FSMA, and the conduct that is prohibited in response to any protected activities. Under FSMA, an employee engaged in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food may not retaliate against an employee because the employee “provided, caused to be provided, or is about to provide or cause to be provided to the employer, the Federal Government, or the attorney general of a State information relating to any violation of, or any act or omission of the employee reasonably believes to be a violation of any provision of this chapter or any order, rule, regulation, standard, or ban under this chapter.” 21 U.S.C. 399d(a)(1). FSMA also protects employees who testify, assist or participate in proceedings concerning such violations. See 21 U.S.C. 399d(a)(2) and (3). Finally, FSMA prohibits retaliation because an employee “objected to, or refused to participate in, any activity, policy, practice, or assigned task that the employee (or other such person) reasonably believed to be in violation of any provision of this chapter, or any order, rule, regulation, standard, or ban under this chapter.” 21 U.S.C. 399d(a)(4).

References to “this chapter” refer to the FD&C, which is chapter 9 of title 21. 21 U.S.C. 301 et seq. Although an entity must therefore be engaged in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food in order to be covered by FSMA, a complainant’s whistleblower activity will be protected when it is based on a reasonable belief that any provision of the FD&C, or any order, rule, regulation, standard, or ban under the FD&C, has been violated.

In order to have a “reasonable belief” under FSMA, a complainant must have both a subjective, good faith belief and an objectively reasonable belief that the complained-of conduct violated the FD&C or any order, rule, regulation, standard, or ban under the FD&C. See Sylvester v. Parexel Int’l LLC, ARB No. 07–123, 2011 WL 2165854, *11–12 (ARB May 25, 2011) (discussing the reasonable belief standard under analogous language in the Sarbanes-Oxley Act whistleblower provision for employees, 18 U.S.C. 1514A). The requirement that the complainant have a subjective, good faith belief is satisfied so long as the complainant actually believed that the conduct complained of violated the relevant law. See id. The objective “reasonableness” of a complainant’s belief is typically determined “based on the knowledge available to a reasonable person in the same factual circumstances with the same training and experience as the aggrieved employee.” Id. at *12 (internal quotation marks and citation omitted). However, the complainant need not show that the conduct complained of constituted an actual violation of law. Pursuant to this standard, an employee’s whistleblower activity is protected where it is based on a reasonable, but mistaken, belief that a violation of the relevant law has occurred. Id. at *13.

No comments were received on this section, and no changes were made to it.

Section 1987.103 Filing of Retaliation Complaint

This section explains the requirements for filing a retaliation complaint under FSMA. According to section 1012(b)(1) of the FD&C, a complaint must be filed within 180 days of when the alleged violation occurs. Under Delaware State College v. Ricks, 449 U.S. 250, 258 (1980), this is considered to be the retaliatory decision has been both made and communicated to the complainant. In other words, the limitations period commences once the employee is aware or reasonably should be aware of the employer’s decision to take an adverse action. See Equal Emp’t Opportunity Comm’n v. United Parcel Serv., Inc., 249 F.3d 557, 561–62 (6th Cir. 2001). The time for filing a complaint may be tolled for reasons warranted by applicable case law. For example, OSHA may consider the time for filing a complaint to be tolled if a complainant mistakenly files a complaint with an agency other than OSHA within 180 days after an alleged adverse action.
Complaints filed under FSMA need not be in any particular form. They may be either oral or in writing. If the complainant is unable to file the complaint in English, OSHA will accept the complaint in any language. With the consent of the employee, complaints may be filed by any person on the employee’s behalf.

OSHA notes that a complaint of retaliation filed with OSHA under FSMA is not a formal document and need not conform to the pleading standards for complaints filed in federal district court articulated in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). See *Sylvestor*, 2011 WL 2165854, at *9–10 (holding whistleblower complaints filed with OSHA under analogous provisions in the Sarbanes-Oxley Act need not conform to federal court pleading standards). Rather, the complaint filed with OSHA under this section simply alerts OSHA to the existence of the alleged retaliation and the complainant’s desire that OSHA investigate the complaint. Upon receipt of the complaint, OSHA is to determine whether the “complaint, supplemented as appropriate by interviews of the complainant” alleges “the existence of facts and evidence to make a prima facie showing.” *See 21 U.S.C. 399d(b)(2)(A)*, 29 CFR 1987.104(e).

No comments were received on this section, and no changes were made to it.

Section 1987.104 Investigation

This section describes the procedures that apply to the investigation of complaints under FSMA. Paragraph (a) of this section outlines the procedures for notifying the parties and the FDA of the complaint and notifying the respondent of its rights under these regulations. Paragraph (b) describes the procedures for the respondent to submit its response to the complaint. Paragraph (c) describes OSHA’s procedures for sharing a party’s submissions during a whistleblower investigation with the other parties to the investigation. Paragraph (d) of this section discusses confidentiality of information provided during investigations.

Paragraph (e) of this section sets forth the applicable burdens of proof. FSMA requires that a complainant make an initial prima facie showing that protected activity was “a contributing factor” in the adverse action alleged in the complaint, i.e., that the protected activity, alone or in combination with other factors, affected in some way the outcome of the employer’s decision. The complainant will be considered to have met the required burden if the complaint on its face, supplemented as appropriate through interviews of the complainant, alleges the existence of facts and either direct or circumstantial evidence to meet the required showing. The complainant’s burden may be satisfied, for example, if he or she shows that the adverse action took place within a temporal proximity of the protected activity, or at the first opportunity available to the respondent, giving rise to the inference that it was a contributing factor in the adverse action. *See, e.g., Porter v. Cal. Dep’t of Corrs.*, 419 F.3d 885, 895 (9th Cir. 2005) (years between the protected activity and the retaliatory actions did not defeat a finding of a causal connection where the defendant did not have the opportunity to retaliate until he was given responsibility for making personnel decisions).

If the complaint does not make the required prima facie showing, the investigation must be discontinued and the complaint dismissed. *See Trimmer v. U.S. Dep’t of Labor*, 174 F.3d 1098, 1101 (10th Cir. 1999) (noting that the burden-shift framework enunciated in *Clarke v. Navaajo Express, Inc.* and *Roll v. U.S. Bd., U.S. Dep’t of Labor*, 402 F. App’x 97, 99 (9th Cir. 2010)) and *Roll* commented that this section of the Energy Reorganization Act of 1974 (ERA), which is the same framework now applicable to FSMA, serves a “gatekeeping function” that “stem[s] frivolous complaints”). Even in cases where the complainant successfully makes a prima facie showing, the investigation must be discontinued if the employer demonstrates, by clear and convincing evidence, that it would have taken the same adverse action in the absence of the protected activity. Thus, OSHA must dismiss a complaint under FSMA and terminates further if either: (1) The complainant fails to meet the prima facie showing that protected activity was a contributing factor in the adverse action; or (2) the employer rebuts that showing by clear and convincing evidence that it would have taken the same adverse action absent the protected activity.

Assuming that an investigation proceeds beyond the gatekeeping phase, the statute requires OSHA to determine whether there is a reasonable cause to believe that protected activity was a contributing factor in the alleged adverse action. A contributing factor is “any factor which, alone or in connection with other factors, tends to affect in any way the outcome of the decision.” *Marano v. Dep’t of Justice*, 2 F.3d 1137, 1140 (Fed. Cir. 1993) (internal quotation marks, emphasis and citation omitted) (discussing the Whistleblower Protection Act, 5 U.S.C. 1221(e)(1)); *see also Addis v. Dep’t of Labor*, 575 F.3d 688, 689–91 (7th Cir. 2009) (discussing Marano as applied to analogous whistleblower provision in the ERA); *Clarke v. Navajo Express, Inc.*, ARB No. 09–114, 2011 WL 2614326, at *3 (ARB June 29, 2011) (discussing burdens of proof under analogous whistleblower provision in the Surface Transportation Assistance Act (STAA)).

For protected activity to be a contributing factor in the adverse action, “a complainant need not necessarily prove that the respondent’s articulated reason was a pretext in order to prevail,” because a complainant alternatively can prevail by showing that the respondent’s “ ‘reason, while true, is only one of the reasons for its conduct,’ ” and that another reason was the complainant’s protected activity. *See Klopfenstein v. PCC Flow Techs. Holdings, Inc.*, ARB No. 04–149, 2006 WL 3246904, at *13 (ARB May 31, 2006) (quoting *Rachid v. Jack in the Box, Inc.*, 376 F.3d 305, 312 (5th Cir. 2004)) (discussing contributing factor test under the Sarbanes-Oxley whistleblower provision), aff’d sub nom. Klopfenstein v. Admin. Review Bd., U.S. Dep’t of Labor, 402 F. App’x 97, 99 (9th Cir. 2010).

If OSHA finds reasonable cause to believe that the alleged protected activity was a contributing factor in the adverse action, OSHA may not order relief if the employer demonstrates by clear and convincing evidence that it would have taken the same action in the absence of the protected activity. *See 21 U.S.C. 399d(b)(2)(C)*. The “clear and convincing evidence” standard is a higher burden of proof than a “preponderance of the evidence” standard. Clear and convincing evidence is evidence that the thing to be proved is highly probable or reasonably certain. *Clarke*, 2011 WL 2614326, at *3.

Paragraph (f) describes the procedures OSHA will follow prior to the issuance of findings and a preliminary order when OSHA has reasonable cause to believe that a violation has occurred.

Roll commented that this section of the IFR did not explicitly state that the respondent has the right to receive copies of the substantive evidence provided by the complainant, and Roll states that it is “essential that both
parties receive equal access to all documents throughout the entire matter." OSHA agrees that the input of both parties in the investigation is important to ensure that OSHA reaches the proper outcome during its investigation. In fact, OSHA’s current policy is to request that each party provide the other parties with a copy of all submissions to OSHA that are pertinent to the whistleblower complaint. Where the parties do not provide each other such submissions, OSHA will ensure that each party is provided with such information after redacting the submissions as appropriate. OSHA has revised paragraph (c) to clarify these policies regarding information sharing during the course of an investigation. Further information regarding OSHA’s nonpublic disclosure and information sharing policies also may be found in the Whistleblower Investigations Manual, available at, http://www.whistleblowers.gov/regulations_page.html.

Roll also commented that the IFR did not provide the complainant and the respondent equal opportunity to respond to the each other’s submissions to OSHA. OSHA has revised paragraph (c) to clarify that OSHA will ensure that each party is provided with an opportunity to respond to the other party’s submissions.

Apart from the changes to paragraph (c) described above, OSHA has reworded paragraphs (a) and (f) slightly to clarify the paragraphs without changing their meaning.

Section 1987.105 Issuance of Findings and Preliminary Orders

This section provides that, on the basis of information obtained in the investigation, the Assistant Secretary will issue, within 60 days of the filing of a complaint, written findings regarding whether or not there is reasonable cause to believe that the complaint has merit. If the findings are that there is reasonable cause to believe that the complaint has merit, the Assistant Secretary will order appropriate relief, including preliminary reinstatement, affirmative action to abate the violation, back pay with interest, and compensatory damages. The findings and, where appropriate, preliminary order, advise the parties of their right to file objections to the findings of the Assistant Secretary and to request a hearing. The findings and, where appropriate, preliminary order, also advise the respondent of the right to request an award of attorney fees not exceeding $1,000 from the ALJ, regardless of whether the respondent has filed objections, if the respondent alleges that the complaint was frivolous or brought in bad faith. If no objections are filed within 30 days of receipt of the findings, the findings and any preliminary order of the Assistant Secretary become the final decision and order of the Secretary. If objections are timely filed, any order of preliminary reinstatement will take effect, but the remaining provisions of the order will not take effect until administrative proceedings are completed.

As explained in the IFR, in ordering interest on back pay under FSMA, the Secretary has determined that interest due will be computed by compounding daily the Internal Revenue Service interest rate for the underpayment of taxes, which under 26 U.S.C. 6621 is generally the Federal short-term rate plus three percentage points. 79 FR 8623. The Secretary has long applied the interest rate in 26 U.S.C. 6621 to calculate interest on backpay in whistleblower cases. Doyle v. Hydro Nuclear Servs., ARB Nos. 99–041, 99–042, 00–012, 2000 WL 694384, at *14–15, 17 (ARB May 17, 2000); see also Cefalu v. Roadway Express, Inc., ARB Nos. 09–070, 2011 WL 1247212, at *2 (ARB Mar. 17, 2011); Pollock v. Cont’l Express, ARB Nos. 07–073, 08–051, 2010 WL 1777697, at *8 (ARB Apr. 19, 2010); Murray v. Air Ride, Inc., ARB Nos. 00–045, slip op. at 9 (ARB Dec. 29, 2000). Section 6621 provides the appropriate measure of compensation under FSMA and other DOL-administered whistleblower statutes because it ensures the complainant will be placed in the same position he or she would have been in if no unlawful retaliation occurred. See Ass’t Sec’y v. Double R. Trucking, Inc., ARB Nos. 99–061, slip op. at 5 (ARB July 16, 1999) (interest awards pursuant to § 6621 are mandatory elements of complainant’s make-whole remedy). Section 6621 provides a reasonably accurate prediction of market outcomes (which represents the loss of investment opportunity by the complainant and the employer’s benefit from use of the withheld money) and thus provides the complainant with appropriate make-whole relief. See EEOC v. Erie Cnty., 751 F.2d 79, 82 (2d Cir. 1984) (“[s]ince the goal of a suit under the Fair Labor Standards Act and the Equal Pay Act is to make whole the victims of the unlawful underpayment of wages, and since § 6621 has been adopted as a good indicator of the value of the use of money, it was well within” the district court’s discretion to impose prejudgment interest under § 6621); New Horizons for the Retarded, 283 N.L.R.B. No. 181, 1987 WL 89652, at *2 (NLRB May 28, 1987) (observing that “the short-term Federal rate [used by § 6621] is based on average market yields on marketable Federal obligations and is influenced by private economic market forces”). Similarly, as explained in the IFR, daily compounding of the interest award ensures that complainants are made whole for unlawful retaliation in violation of FSMA. 79 FR 8623.

As explained in the IFR, in ordering back pay, OSHA will require the respondent to submit the appropriate documentation to the Social Security Administration (SSA) allocating the back pay to the appropriate calendar quarters. Requiring the reporting of back pay allocation to the SSA serves the remedial purposes of FSMA by ensuring that employees subjected to retaliation are truly made whole. See 79 FR 8623; see also Don Chavas, LLC d/b/a Tortillas Don Chavas, 361 NLRB No. 10, 2014 WL 3897178, at *4–5 (NLRB Aug. 8, 2014).

Finally, as noted in the IFR, in limited circumstances, in lieu of preliminary reinstatement, OSHA may order that the complainant receive the same pay and benefits that he or she received prior to termination, but not actually return to work. See 79 FR 8623. Such “economic reinstatement” is akin to an order for front pay and frequently is employed in cases arising under section 105(c) of the Federal Mine Safety and Health Act of 1977, which protects miners from retaliation. 30 U.S.C. 815(c); see, e.g., Sec’y of Labor ex rel. York v. BR&D Enters., Inc., 23 FMSHRC 697, 2001 WL 1806020, at *1 (ALJ June 26, 2001). Front pay has been recognized as a possible remedy in cases under the whistleblower statutes enforced by OSHA in limited circumstances where reinstatement would not be appropriate. See, e.g., Luder v. Cont’l Airlines, Inc., ARB No. 10–026, 2012 WL 376755, at *11 (ARB Jan. 31, 2012), aff’d, Cont’l Airlines, Inc. v. Admin. Rev. Bd., No. 15–60012, slip op. at 8, 2016 WL 97461, at *4 (5th Cir. Jan. 7, 2016) (unpublished) (under Wendell H. Ford Aviation Investment and Reform Act for the 21st Century, “front-pay is available when reinstatement is not possible”); Moder v. Vill. of Jackson, ARB Nos. 01–095, 02–039, 2003 WL 21499864, at *10 (ARB June 30, 2003) (under environmental whistleblower statutes, “front pay may be an appropriate substitute when the parties prove the impossibility of a productive and amicable working relationship, or the company no longer has a position for which the complainant is qualified”). Roll commented on the discussion in the IFR of “economic reinstatement”
and front pay and suggested that OSHA should include specific guidelines pertaining to front pay awards. Roll noted that the IFR provided examples of situations where front pay might be appropriate, but the rules themselves do not explicitly state that front pay is an available remedy, which could be "misleading." Further, Roll questioned whether OSHA has authority to order front pay as a remedy.

OSHA declines to adopt specific guidelines pertaining to front pay awards in these rules. As explained in the IFR, the appropriateness of "economic reinstatement" or front pay as an alternative to the default statutory remedy of reinstatement has long been recognized. OSHA believes that relevant case law more appropriately addresses the parameters for issuing an award of front pay in lieu of reinstatement. See, e.g., Luder, ARB No. 10–026, slip op. at *11. (holding that front pay must be awarded according to reasonable parameters such as the amount of the proposed award, the length of time the complainant expects to be out of work, and the applicable discount rate) (internal quotation marks and citations omitted), front pay award modified. Luder v. Cont'l Airlines, Inc., ARB No. 13–009, 2014 WL 6850012 (ARB Nov. 2014), aff'd, Cont'l Airlines, Inc. v. Admin. Review Bd., No. 15–60012, slip op. at 8, 2016 WL 97461, at *4 (5th Cir. Jan. 7, 2016) (unpublished).

Kalijarvi requested that the rule include a reference to Blackburn v. Martin, 982 F.2d 125 (4th Cir. 1992) to inform the public that emotional distress damages may be awarded without the testimony of expert witnesses. A number of ARB decisions have awarded such damages without the testimony of expert witnesses in appropriate circumstances. See e.g., Lockheed Martin Corp. v. Admin. Review Bd., 717 F.3d 1121, 1138 (10th Cir. 2013) (upholding an award of $75,000 for emotional pain and suffering without requiring the testimony of expert witnesses); Menendez v. Halliburton, Inc., ARB Nos 09–002, 09–003 2013 WL 1282255, at *11–12 (ARB Mar. 15, 2013) (upholding award of $30,000 for emotional distress and reputational harm without requiring expert testimony) aff'd sub nom. Halliburton, Inc. v. Admin. Review Bd., 771 F.3d 254 (5th Cir. 2014). OSHA believes that these cases adequately serve to notify the public that emotional distress damages may be awarded without the testimony of expert witnesses.

For these reasons, OSHA has made no changes to the text of this section.

Subpart B—Ligation

Section 1987.106 Objections to the Findings and the Preliminary Order and Requests for a Hearing

To be effective, objections to the findings of the Assistant Secretary must be in writing and must be filed with the Chief Administrative Law Judge, U.S. Department of Labor, within 30 days of receipt of the findings. The date of the postmark, facsimile transmittal, or electronic communication transmittal is considered the date of the filing; if the objection is filed in person, by hand-delivery or other means, the objection is filed upon receipt. The filing of objections also is considered a request for a hearing before an ALJ. Although the parties are directed to serve a copy of their objections on the other parties of record, as well as the OSHA official who issued the findings and order, the Assistant Secretary, and the U.S. Department of Labor's Associate Solicitor for Fair Labor Standards, the failure to serve copies of the objections on the other parties of record does not affect the ALJ's jurisdiction to hear and decide the merits of the case. See Shirani v. Calvert Cliffs Nuclear Power Plant, Inc., ARB No. 04–101, 2005 WL 2865915, at *7 (ARB Oct. 31, 2005). The timely filing of objections stays all provisions of the preliminary order, except for the portion requiring reinstatement. A respondent may file a motion to stay the Assistant Secretary's preliminary order of reinstatement with the Office of Administrative Law Judges. However, such a motion will be granted only based on exceptional circumstances. The Secretary believes that a stay of the Assistant Secretary's preliminary order of reinstatement under FSMA would be appropriate only where the respondent can establish the necessary criteria for equitable injunctive relief, i.e., irreparable injury, likelihood of success on the merits, a balancing of possible harms to the parties, and the public interest favors a stay. If no timely objection to the Assistant Secretary's findings and/or preliminary order is filed, then the Assistant Secretary's findings and/or preliminary order become the final decision of the Secretary not subject to judicial review.

No comments were received on this section, and no changes were made to it.

Section 1987.107 Hearings

This section adopts the rules of practice and procedure for administrative hearings before the Office of Administrative Law Judges as set forth in 29 CFR part 18 subpart A. This section provides that the hearing is to commence expeditiously, except upon a showing of good cause or unless otherwise agreed to by the parties. Hearings will be conducted de novo, on the record. As noted in this section, formal rules of evidence will not apply, but rules or principles designed to assure production of the most probative evidence will be applied. The ALJ may exclude evidence that is immaterial, irrelevant, or unduly repetitious.

No comments were received on this section, and no changes were made to it.

Section 1987.108 Role of Federal Agencies

The Assistant Secretary, at his or her discretion, may participate as a party or amicus curiae at any time in the administrative proceedings under FSMA. For example, the Assistant Secretary may exercise his or her discretion to prosecute the case in the administrative proceeding before an ALJ; petition for review of a decision of an ALJ, including a decision based on a settlement agreement between the complainant and the respondent, regardless of whether the Assistant Secretary participated before the ALJ; or participate as amicus curiae before the ALJ or in the ARB proceeding. Although OSHA anticipates that ordinarily the Assistant Secretary will not participate, the Assistant Secretary may choose to do so in appropriate cases, such as cases involving important or novel legal issues, multiple employees, alleged violations that appear egregious, or where the interests of justice might require participation by the Assistant Secretary. The FDA, if interested in a proceeding, also may participate as amicus curiae at any time in the proceedings.

No comments were received on this section, though minor changes were made as needed to clarify the provision without changing its meaning.

Section 1987.109 Decision and Orders of the Administrative Law Judge

This section sets forth the requirements for the content of the decision and order of the ALJ, and includes the standard for finding a violation under FSMA. Specifically, the complainant must demonstrate (i.e., prove by a preponderance of the evidence) that the protected activity was a "contributing factor" in the adverse action. See, e.g., Allen v. Admin. Review Bd., 514 F.3d 468, 475 n.1 (5th Cir. 2008) (*The term ‘demonstrates’ [under identical burden-shifting scheme in the Sarbanes-Oxley whistleblower provision] means to prove by a
Electronic communication transmittal is considered the date of filing of the petition; if the petition is filed in person, by hand delivery or other means, the petition is considered filed upon receipt.

The appeal provisions in this part provide that an appeal to the ARB is not a matter of right but is accepted at the discretion of the ARB. The parties should identify in their petitions for review the legal conclusions or orders to which they object, or the objections may be deemed waived. The ARB has 30 days to decide whether to grant the petition for review. If the ARB does not grant the petition, the decision of the ALJ becomes the final decision of the Secretary. If a timely petition for review is filed with the ARB, any relief ordered by the ALJ, except for that portion ordering reinstatement, is inoperative while the matter is pending before the ARB. If the ARB accepts a petition for review, the ALJ’s factual determinations will be reviewed under the substantial evidence standard.

Kalijarvi submitted several comments related to this section of the rule. Kalijarvi requested the removal of the portion of the rule stating that objections not raised in the petition for review to the ARB may be considered waived. Instead, Kalijarvi requested that the provision be altered to instruct parties to identify in their petitions for review the legal conclusions or orders to which they object so that the ARB may determine whether the review presents issues worthy of full briefing. OSHA declines to revise the rule as Kalijarvi has proposed. OSHA notes that the IFR used the phrase “may” be deemed waived, indicating that the parties are not necessarily barred from subsequently raising grounds in addition to those included in the initial petition. Further, OSHA’s inclusion of this provision is not intended to limit the circumstances in which parties can add additional grounds for review as a case progresses before the ARB; rather, the rules include this provision to put the public on notice of the possible consequences of failing to specify the basis of an appeal to the ARB. OSHA recognizes that, while the ARB has held in some instances that an exception not specifically urged may be deemed waived, the ARB also has found that the rules provide for exceptions to this general rule.

Kalijarvi also requested that the deadline for filing a petition for review with the ARB be extended past 14 days, and for this section to allow explicitly for the parties to file a motion to extend the time for submitting a petition for review. Kalijarvi further requested that OSHA explain how the current text of the section furthers FSMA’s remedial purpose. OSHA declines to extend the time limit to petition for review because the shorter review period is consistent with the practices and procedures followed in OSHA’s other whistleblower programs. Furthermore, as Kalijarvi acknowledges in its comment, parties may file a motion for extension of time to appeal an ALJ’s decision, and the ARB has discretion to grant such extensions. OSHA believes that mentioning a motion for an extension of time in these rules, where no other motions are mentioned, could lead the public to mistakenly conclude that the 14 day deadline may be waived as a matter of right, where such is not the case.

OSHA believes that this section furthers the remedial purpose of FSMA by informing the public of the option of requesting ARB review of ALJ decisions as well as the deadlines associated with such review.

This section also provides that, based on exceptional circumstances, the ARB may grant a motion to stay an ALJ’s preliminary order of reinstatement under FSMA, which otherwise would be effective, while review is conducted by the ARB. The Secretary believes that a stay of an ALJ’s preliminary order of reinstatement under FSMA would be appropriate only where the respondent can establish the necessary criteria for equitable injunctive relief, i.e., irreparable injury, likelihood of success on the merits, a balancing of possible harms to the parties, and the public interest favors a stay.

If the ARB concludes that the respondent has violated the law, it will order the respondent to take appropriate affirmative action to abate the violation, including reinstatement of the complainant to that person’s former position, together with the compensation (including back pay and interest), terms, conditions, and privileges of employment, and compensatory damages. At the request of the complainant, the ARB will assess against the respondent all costs and expenses (including attorney and expert witness fees) reasonably incurred. Interest on back pay will be calculated using the interest rate applicable to underpayment of taxes under 26 U.S.C. 6621 and will be compounded daily, and the respondent will be required to submit appropriate documentation to the Social Security Administration (SSA) allocating any back pay award to the SSA.

Section 1987.150 Petition for Review

Upon the issuance of the ALJ’s decision, the parties have 14 days within which to petition the ARB for review of that decision. The date of the postmark, facsimile transmittal, or electronic communication transmittal is considered the date of filing of the petition; if the petition is filed in person, by hand delivery or other means, the petition is considered filed upon receipt.

The appeal provisions in this part provide that an appeal to the ARB is not a matter of right but is accepted at the discretion of the ARB. The parties should identify in their petitions for review the legal conclusions or orders to which they object, or the objections may be deemed waived. The ARB has 30 days to decide whether to grant the petition for review. If the ARB does not grant the petition, the decision of the ALJ becomes the final decision of the Secretary. If a timely petition for review is filed with the ARB, any relief ordered by the ALJ, except for that portion ordering reinstatement, is inoperative while the matter is pending before the ARB. If the ARB accepts a petition for review, the ALJ’s factual determinations will be reviewed under the substantial evidence standard.

Kalijarvi submitted several comments related to this section of the rule. Kalijarvi requested the removal of the portion of the rule stating that objections not raised in the petition for review to the ARB may be considered waived. Instead, Kalijarvi requested that the provision be altered to instruct parties to identify in their petitions for review the legal conclusions or orders to which they object so that the ARB may determine whether the review presents issues worthy of full briefing. OSHA declines to revise the rule as Kalijarvi has proposed. OSHA notes that the IFR used the phrase “may” be deemed waived, indicating that the parties are not necessarily barred from subsequently raising grounds in addition to those included in the initial petition. Further, OSHA’s inclusion of this provision is not intended to limit the circumstances in which parties can add additional grounds for review as a case progresses before the ARB; rather, the rules include this provision to put the public on notice of the possible consequences of failing to specify the basis of an appeal to the ARB. OSHA recognizes that, while the ARB has held in some instances that an exception not specifically urged may be deemed waived, the ARB also has found that the rules provide for exceptions to this general rule.

Kalijarvi also requested that the deadline for filing a petition for review with the ARB be extended past 14 days, and for this section to allow explicitly for the parties to file a motion to extend the time for submitting a petition for review. Kalijarvi further requested that OSHA explain how the current text of the section furthers FSMA’s remedial purpose. OSHA declines to extend the time limit to petition for review because the shorter review period is consistent with the practices and procedures followed in OSHA’s other whistleblower programs. Furthermore, as Kalijarvi acknowledges in its comment, parties may file a motion for extension of time to appeal an ALJ’s decision, and the ARB has discretion to grant such extensions. OSHA believes that mentioning a motion for an extension of time in these rules, where no other motions are mentioned, could lead the public to mistakenly conclude that the 14 day deadline may be waived as a matter of right, where such is not the case.

OSHA believes that this section furthers the remedial purpose of FSMA by informing the public of the option of requesting ARB review of ALJ decisions as well as the deadlines associated with such review.

This section also provides that, based on exceptional circumstances, the ARB may grant a motion to stay an ALJ’s preliminary order of reinstatement under FSMA, which otherwise would be effective, while review is conducted by the ARB. The Secretary believes that a stay of an ALJ’s preliminary order of reinstatement under FSMA would be appropriate only where the respondent can establish the necessary criteria for equitable injunctive relief, i.e., irreparable injury, likelihood of success on the merits, a balancing of possible harms to the parties, and the public interest favors a stay.

If the ARB concludes that the respondent has violated the law, it will order the respondent to take appropriate affirmative action to abate the violation, including reinstatement of the complainant to that person’s former position, together with the compensation (including back pay and interest), terms, conditions, and privileges of employment, and compensatory damages. At the request of the complainant, the ARB will assess against the respondent all costs and expenses (including attorney and expert witness fees) reasonably incurred. Interest on back pay will be calculated using the interest rate applicable to underpayment of taxes under 26 U.S.C. 6621 and will be compounded daily, and the respondent will be required to submit appropriate documentation to the Social Security Administration (SSA) allocating any back pay award to the SSA.
the request of the respondent, the ARB determines that a complaint was frivolous or was brought in bad faith, the ARB may award to the respondent a reasonable attorney fee, not exceeding $1,000, to be paid by the complainant.

No changes were made to this section, and other than the comments discussed above, no additional comments were received on this section.

Subpart C—Miscellaneous Provisions

Section 1987.111 Withdrawal of Complaints, Findings, Objections, and Petitions for Review: Settlement

This section provides the procedures and time periods for withdrawal of complaints, the withdrawal of findings and/or preliminary orders by the Assistant Secretary, and the withdrawal of objections to findings and/or orders. It permits complainants to withdraw their complaints orally and provides that, in such circumstances, OSHA will confirm a complainant’s desire to withdraw in writing. It also provides for approval of settlements at the investigative and adjudicative stages of the case.

Roll commented that this provision should state explicitly that settlements may be conducted in a confidential manner and outside of the administrative proceedings. Because the IFR did not plainly provide such assurances, Roll expressed concern that “the lack of confidentiality will work as a disincentive for both parties. . . .” Roll further commented that this section should include guidelines regarding when the Secretary will approve or disapprove a settlement agreement, as well as an explanation regarding the settlement options that are available to the parties.

OSHA is not making any changes to the rule in response to this comment. This section implements FSMA’s statutory provision that “[a]ll any time before issuance of a final order, a proceeding under this subsection may be terminated on the basis of a settlement agreement entered into by the Secretary, the complainant, and the person alleged to have committed the violation.” 21 U.S.C. 399(b)(3)(A).

However, OSHA notes that the Secretary has always recognized that parties may efficiently resolve cases in negotiations between themselves. The Secretary’s policy is to approve privately negotiated settlements, provided that each settlement is reviewed by the Secretary to ensure that the terms are fair, adequate, reasonable, and consistent with the purpose and intent of the relevant whistleblower statute and the public interest. See, e.g., Macktal v. Sec’y of Labor, 923 F.2d 1150, 1154 (5th Cir. 1991) (agreeing that the Secretary may “enter into” a settlement by approving a settlement negotiated and agreed to by the parties); see also OSHA’s Whistleblower Investigations Manual, pp. 6–18 to 6–21 (Apr. 21, 2015) available at http://www.whistleblowers.gov/regulations_page.html. OSHA believes that paragraphs (d)(1) and (2) adequately explain that a settlement agreement reached between the parties will settle a pending whistleblower case so long as the agreement is reviewed and approved by OSHA, an ALJ, or the ARB. The resources listed above provide more detailed guidance on when OSHA, an ALJ or the ARB will approve or disapprove a settlement agreement, and OSHA thus believes it unnecessary to add such additional details to the regulatory text.

As to Roll’s confidentiality concerns, OSHA, an ALJ or the ARB will not approve an agreement that states or implies that any of these entities, or DOL more generally, is party to a confidentiality agreement. Moreover, as noted in paragraph (o) of this section, any settlement approved by OSHA, the ALJ, or the ARB will constitute the final order of the Secretary, and as such, an approved agreement is an official government record that is subject to applicable public disclosure rules. See, e.g., Gonzalez v. J.C. Penny Corp., Inc., ARB No. 10–148, 2012 WL 4753923, at *6 [ARB Sept. 28, 2012] (describing the public interest supporting the Secretary’s review of settlement agreements); McGuire v. B.P. Prods. N. Am., Inc., 2014–TSC–0001, slip op. at 6–11 [ALJ Jan. 17, 2014] (describing public disclosure interests relating to whistleblower settlements and some of the provisions that the Secretary may not approve in a whistleblower settlement). Thus, for example, while parties may negotiate the terms of a settlement agreement in confidence and may indicate to OSHA, an ALJ or the ARB that they believe a settlement contains information exempt from disclosure under the Freedom of Information Act (FOIA) and that they should receive pre-disclosure notification of a request for disclosure, the Secretary must make its own determination of whether the contents of a settlement may be withheld in response to a request from a member of the public. See, e.g., Vannoy v. Celanese Corp., ARB No. 09–118, 2013 WL 5872048, at *2 [ARB Sept. 27, 2013] (describing the application of FOIA to a whistleblower settlement).

Section 1987.112 Judicial Review

This section describes the statutory provisions for judicial review of decisions of the Secretary and requires, in cases where judicial review is sought, the ALJ or the ARB to submit the record of proceedings to the appropriate court pursuant to the rules of such court. No comments were received on this section, and no changes were made to it.

Section 1987.113 Judicial Enforcement

This section describes the Secretary’s power under FSMA to obtain judicial enforcement of orders and the terms of settlement agreements. FSMA expressly authorizes district courts to enforce orders, including preliminary orders of reinstatement, issued by the Secretary.

See 21 U.S.C. 399(d)(b)(6) (“Whenever any person has failed to comply with an order issued under paragraph (3), the Secretary may file a civil action in the United States district court for the district in which the violation was found to occur, or in the United States district court for the District of Columbia, to enforce such order.”). Specifically, reinstatement orders issued at the close of OSHA’s investigation are immediately enforceable in district court pursuant to 21 U.S.C. 399(d)(b)(6) and (7). FSMA provides that the Secretary shall order the person who has committed a violation to reinstate the complainant to his or her former position. See 21 U.S.C. 399(d)(b)(3)(B)(i). FSMA also provides that the Secretary shall accompany any reasonable cause finding that a violation occurred with a preliminary order containing the relief prescribed by subsection (b)(3)(B), which includes reinstatement where appropriate, and that any preliminary order of reinstatement shall not be stayed upon the filing of objections. See 21 U.S.C. 399(d)(b)(2)(B) (“The filing of such objections shall not operate to stay any reinstatement remedy contained in the preliminary order.”). Thus, under FSMA, enforceable orders include preliminary orders that contain the relief of reinstatement prescribed by 21 U.S.C. 399(d)(b)(3)(B). This statutory interpretation is consistent with the Secretary’s interpretation of similar language in the whistleblower provisions of the Wendell H. Ford Aviation Investment and Reform Act for the 21st Century, 49 U.S.C. 42121, and Section 806 of the Corporate and Criminal Fraud Accountability Act of 2002, Title VIII of the Sarbanes-Oxley Act of 2002, 18 U.S.C. 1514A. See Brief for the Intervenor/Plaintiff Appellee Secretary of Labor, Solis v. Tenn. Commerce Bancorp, Inc., No. 10–5602.
This section sets forth provisions that allow a complainant to bring an original de novo action in district court, alleging the same allegations contained in the complaint filed with OSHA, under certain circumstances. FSMA permits a complainant to file a new de novo review in the appropriate district court if there has been no final decision of the Secretary within 210 days of the filing of the complaint, or within 90 days after receiving a written determination. “Written determination” refers to the Assistant Secretary’s written findings issued at the close of OSHA’s investigation under section 1987.105(a). See 21 U.S.C. 399d(b)(4). The Secretary’s final decision is generally the decision of the ARB issued under section 1987.110. In other words, a complainant may file an action for de novo review in the appropriate district court in either of the following two circumstances: (1) A complainant may file a de novo action in district court within 90 days of receiving the Assistant Secretary’s written findings issued under section 1987.105(a), or (2) a complainant may file a de novo action in district court if more than 210 days have passed since the filing of the complaint and the Secretary has not issued a final decision. The plain language of 21 U.S.C. 399d(b)(4), by distinguishing between actions that can be brought if the Secretary has not issued a “final decision” within 210 days and actions that can be brought within 90 days after a “written determination,” supports allowing de novo actions in district court under either of the circumstances described above.

However, the Secretary believes that FSMA does not permit complainants to initiate an action in federal court after the Secretary’s final decision, even if the date of the final decision is more than 210 days after the filing of the complaint or within 90 days of the complainant’s receipt of the Assistant Secretary’s written findings. The purpose of the “kick-out” provision is to aid the complainant in receiving a prompt decision. That goal is not implicated in a situation where the complainant already has received a final decision from the Secretary. In addition, permitting the complainant to file a new case in district court in such circumstances conflicts with the parties’ right to seek judicial review of the Secretary’s final decision in the court of appeals. See 21 U.S.C. 399d(b)(5)(B) (providing that an order with respect to which review could have been obtained in the court of appeals shall not be subject to judicial review in any criminal or other civil proceeding).

This section also requires that, within seven days after filing a complaint in district court, a complainant must provide a file-stamped copy of the complaint to OSHA, the ALJ, or the ARB, depending on where the proceeding is pending. In all cases, a copy of the complaint also must be provided to the OSHA official who issued the findings and/or preliminary order, the Assistant Secretary, and the U.S. Department of Labor’s Associate Solicitor for Fair Labor Standards. This provision is necessary to notify the agency that the complainant has opted to file a complaint in district court. This provision is not a substitute for the complainant’s compliance with the requirements for service of process of the district court complaint contained in the Federal Rules of Civil Procedure and the local rules of the district court where the complaint is filed. This section also incorporates the statutory provisions which allow for a jury trial at the request of either party in a district court action, and which specify the remedies and burdens of proof in a district court action.

In response to the IFR preamble’s statement that the purpose of the “kick-out” provision is to “aid the complainant in receiving a prompt decision,” Kalijarvi commented that the kick-out provision offers additional benefits and is such an opportunity to receive a jury determination of damages. Indeed, Paragraph (a) of this section provides that an action brought under this section is entitled to trial by jury. OSHA appreciates Kalijarvi’s comment, but has left the text of the rule unchanged.

This section provides that in circumstances not contemplated by these rules or for good cause the ALJ or the ARB may, upon application and notice to the parties, waive any rule as justice or the administration of FSMA requires. No comments were received on this section, and no changes were made to it.

IV. Paperwork Reduction Act

This rule contains a reporting provision (filing a retaliation complaint, Section 1987.103) which was previously reviewed and approved for use by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The assigned OMB control number is 1218–0236.

V. Administrative Procedure Act

The notice and comment rulemaking procedures of section 553 of the Administrative Procedure Act (APA) do not apply “to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice.” 5 U.S.C. 553(b)(A). This is a rule of agency procedure, practice, and interpretation within the meaning of that section, since it provides procedures for the Department’s handling of retaliation complaints. Therefore, publication in the Federal Register of a notice of proposed rulemaking and request for comments are not required for these regulations. Although this rule is not subject to the notice and comment procedures of the APA, the Assistant Secretary sought and considered comments to enable the agency to improve the rules by taking into account the concerns of interested persons.

Furthermore, because this rule is procedural and interpretative rather than substantive, the normal requirement of 5 U.S.C. 553(d) that a rule be effective immediately so both parties may know what procedures are applicable to pending cases.
VI. Executive Orders 12866 and 13563; Unfunded Mandates Reform Act of 1995; Executive Order 13132

The Department has concluded that this rule is not a “significant regulatory action” within the meaning of section 3(f)(4) of Executive Order 12866, as reaffirmed by Executive Order 13563, because it is not likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affects a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in Executive Order 12866. Therefore, no regulatory impact analysis under Section 6(a)(3)(C) of Executive Order 12866 has been prepared.

For this reason, and because no notice of proposed rulemaking has been published, no statement is required under Section 202 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1531 et seq. Finally, this rule does not have “federalism implications.” The rule does not have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government” and therefore is not subject to Executive Order 13132 (Federalism).

VII. Regulatory Flexibility Analysis

The notice and comment rulemaking procedures of Section 553 of the APA do not apply “to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice,” 5 U.S.C. 553(b)(A). Rules that are exempt from APA notice and comment requirements are also exempt from the Regulatory Flexibility Act (RFA). See SBA Office of Advocacy, A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act 9 (May 2012); also found at: http://www.sba.gov/sites/default/files/rfiguide_0512_0.pdf. This is a rule of agency procedure, practice, and interpretation within the meaning of that section; therefore, the rule is exempt from both the notice and comment rulemaking procedures of the APA and the requirements under the RFA.

List of Subjects in 29 CFR Part 1987

Administrative practice and procedure, Employment, Food safety, Investigations, Reporting and recordkeeping requirements, Whistleblower.

Authority and Signature

This document was prepared under the direction and control of David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health.

Signed at Washington, DC, on April 11, 2016.

David Michaels,
Assistant Secretary of Labor for Occupational Safety and Health.

Accordingly, for the reasons set out in the preamble, 29 CFR part 1987 is revised to read as follows:

PART 1987—PROCEDURES FOR HANDLING RETALIATION COMPLAINTS UNDER SECTION 402 OF THE FDA FOOD SAFETY MODERNIZATION ACT

Subpart A—Complaints, Investigations, Findings and Preliminary Orders

1987.100 Purpose and scope.
1987.102 Obligations and prohibited acts.
1987.103 Filing of retaliation complaint.
1987.106 Objections to the findings and the preliminary order, rule, regulation, standard, or ban alleged violation of the FD&C, or any activity pertaining to a violation or alleged violation of the FD&C, or any order, rule, regulation, standard, or ban under the FD&C.
1987.109 Decision and orders of the administrative law judge.

Subpart B—Litigation

1987.111 Withdrawal of complaints, findings, objections, and petitions for review; settlement.
1987.112 Judicial review.
1987.113 Judicial enforcement.
1987.115 Special circumstances; waiver of rules.

[g] FDA means the Food and Drug Administration of the United States Department of Health and Human Services.
(h) Food means articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such article.
(j) OSHA means the Occupational Safety and Health Administration of the United States Department of Labor.
(k) Person includes an individual, partnership, corporation, and association.
(l) Respondent means the employer named in the complaint who is alleged to have violated the FSMA.
(m) Secretary means the Secretary of Labor or person to whom authority under the FSMA has been delegated.
(n) Any future statutory amendments that affect the definition of a term or terms listed in this section will apply in lieu of the definition stated herein.
§ 1987.102 Obligations and prohibited acts.
(a) No covered entity may discharge or otherwise retaliate against, including, but not limited to, intimidating, threatening, restraining, coercing, blacklisting or disciplining, any employee with respect to the employee’s compensation, terms, conditions, or privileges of employment because the employee, whether at the employee’s initiative or in the ordinary course of the employee’s duties (or any person acting pursuant to a request of the employee), has engaged in any of the activities specified in paragraphs (b) through (f) of this section.
(b) An employee is protected against retaliation because the employee (or any person acting pursuant to a request of the employee) has:
(1) Provided, caused to be provided, or is about to provide or cause to be provided to the employer, the Federal Government, or the attorney general of a State information relating to any violation of, or any act or omission the employee reasonably believes to be a violation of any provision of the FD&C or any order, rule, regulation, standard, or ban under the FD&C;
(2) Testified or is about to testify in a proceeding concerning such violation;
(3) Assisted or participated or is about to assist or participate in such a proceeding; or
(4) Objected to, or refused to participate in, any activity, policy, practice, or assigned task that the employee (or other such person) reasonably believed to be in violation of any provision of the FD&C, or any order, rule, regulation, standard, or ban under the FD&C.
§ 1987.103 Filing of retaliation complaint.
(a) Who may file. An employee who believes that he or she has been retaliated against in violation of FSMA may file, or have filed by any person on the employee’s behalf, a complaint alleging such retaliation.
(b) Nature of filing. No particular form of complaint is required. A complaint may be filed orally or in writing. Oral complaints will be reduced to writing by OSHA. If the complainant is unable to file the complaint in English, OSHA will accept the complaint in any language.
(c) Place of filing. The complaint should be filed with the OSHA office responsible for enforcement activities in the geographical area where the employee resides or was employed, but may be filed with any OSHA officer or employee. Addresses and telephone numbers for these officials are set forth in local directories and at the following Internet address: http://www.osha.gov.
(d) Time for filing. Within 180 days after an alleged violation of FSMA occurs, any employee who believes that he or she has been retaliated against in violation of that section may file, or have filed by any person on the employee’s behalf, a complaint alleging such retaliation. The date of the postmark, facsimile transmittal, electronic communication transmittal, telephone call, hand-delivery, delivery to a third-party commercial carrier, or in-person filing at an OSHA office will be considered the date of filing. The time for filing a complaint may be tolled for reasons warranted by applicable case law. For example, OSHA may consider the time for filing a complaint to be tolled if a complaint mistakenly files a complaint with an agency other than OSHA within 180 days after an alleged adverse action.
§ 1987.104 Investigation.
(a) Upon receipt of a complaint in the investigating office, OSHA will notify the respondent of the filing of the complaint, of the allegations contained in the complaint, and of the substance of the evidence supporting the complaint. Such materials will be redacted, if necessary, consistent with the Privacy Act of 1974, 5 U.S.C. 552a, and other applicable confidentiality laws. OSHA will also notify the respondent of its rights under paragraphs (b) and (f) of this section and § 1987.110(e). OSHA will provide an unredacted copy of these same materials to the complainant (or the complainant’s legal counsel if complainant is represented by counsel) and to the FDA.
(b) Within 20 days of receipt of the notice of the filing of the complaint provided under paragraph (a) of this section, the respondent and the complainant each may submit to OSHA a written statement and any affidavits or documents substantiating its position. Within the same 20 days, the respondent and the complainant each may request a meeting with OSHA to present its position.
(c) During the investigation, OSHA will request that each party provide the other parties to the whistleblower complaint with a copy of submissions to OSHA that are pertinent to the whistleblower complaint. Alternatively, if a party does not provide its submissions to OSHA to the other party, OSHA will provide them to the other party (or the party’s legal counsel if the party is represented by counsel) at a time permitting the other party an opportunity to respond. Before providing such materials to the other party, OSHA will redact them, if necessary, consistent with the Privacy Act of 1974, 5 U.S.C. 552a, and other applicable confidentiality laws. OSHA will also provide each party with an opportunity to respond to the other party’s submissions.
(d) Investigations will be conducted in a manner that protects the confidentiality of any person who provides information on a confidential basis, other than the complainant, in accordance with part 70 of this title.
(e)(1) A complaint will be dismissed unless the complainant has made a prima facie showing (i.e., a non-frivolous allegation) that a protected activity was a contributing factor in the adverse action alleged in the complaint.
(2) The complaint, supplemented as appropriate by interviews of the complainant, must allege the existence of facts and evidence to make a prima facie showing as follows:
(i) The employee engaged in a protected activity;
(ii) The respondent knew or suspected that the employee engaged in the protected activity;
(iii) The employee suffered an adverse action; and
(iv) The circumstances were sufficient to raise the inference that the protected activity was a contributing factor in the adverse action.
(3) For purposes of determining whether to investigate, the complainant will be considered to have met the required burden if the complaint on its
necessary, consistent with the Privacy Act of 1974, 5 U.S.C. 552a, and other applicable confidentiality laws. The respondent will be given the opportunity to submit a written response, to meet with the investigators, to present statements from witnesses in support of its position, and to present legal and factual arguments. The respondent must present this evidence within 10 business days of OSHA's notification pursuant to this paragraph, or as soon thereafter as OSHA and the respondent can agree, if the interests of justice so require.


(a) After considering all the relevant information collected during the investigation, the Assistant Secretary will issue, within 60 days of the filing of the complaint, written findings as to whether or not there is reasonable cause to believe that the respondent has retaliated against the complainant in violation of FSMA.

(1) If the Assistant Secretary concludes that there is reasonable cause to believe that a violation has occurred, the Assistant Secretary will accompany the findings with a preliminary order providing relief to the complainant. The preliminary order will require, where appropriate: Affirmative action to abate the violation; reinstatement of the complainant to his or her former position, together with the compensation (including back pay and interest), terms, conditions and privileges of the complainant's employment; and payment of compensatory damages, including, at the request of the complainant, the aggregate amount of all costs and expenses (including attorney and expert witness fees) reasonably incurred. Interest on back pay will be calculated using the interest rate applicable to underpayment of taxes under 26 U.S.C. 6621 and will be compounded daily. The preliminary order will also require the respondent to submit appropriate documentation to the Social Security Administration allocating any back pay award to the appropriate calendar quarters.

(2) If the Assistant Secretary concludes that a violation has not occurred, the Assistant Secretary will notify the parties of that finding.

(b) The findings and, where appropriate, the preliminary order will be sent by certified mail, return receipt requested (or other means that allow OSHA to confirm receipt), to all parties of record (and each party's legal counsel if respondent is represented by counsel). The findings and, where appropriate, the preliminary order will inform the parties of the right to object to the findings and/or order and to request a hearing, and of the right of the respondent to request an award of attorney fees not exceeding $1,000 from the administrative law judge (ALJ), regardless of whether the respondent has filed objections, if the respondent alleges that the complaint was frivolous or brought in bad faith. The findings and, where appropriate, the preliminary order also will give the address of the Chief Administrative Law Judge, U.S. Department of Labor. At the same time, the Assistant Secretary will file with the Chief Administrative Law Judge a copy of the original complaint and a copy of the findings and/or order.

(c) The findings and any preliminary order will be effective 30 days after receipt by the respondent (or the respondent's legal counsel if the respondent is represented by counsel), or on the compliance date set forth in the preliminary order, whichever is later, unless an objection and/or a request for hearing has been timely filed as provided at § 1987.106. However, the portion of any preliminary order requiring reinstatement will be effective immediately upon the respondent's receipt of the findings and the preliminary order, regardless of any objections to the findings and/or the order.

Subpart B—Litigation

§1987.106 Objections to the findings and the preliminary order and requests for a hearing.

(a) Any party who desires review, including judicial review, of the findings and/or preliminary order, or a respondent alleging that the complaint was frivolous or brought in bad faith who seeks an award of attorney fees under FSMA, must file any objections and/or a request for a hearing on the record within 30 days of receipt of the findings and preliminary order pursuant to §1987.105. The objections, request for a hearing, and/or request for attorney fees must be in writing and state whether the objections are to the findings, the preliminary order, and/or whether there should be an award of attorney fees.

The date of the postmark, facsimile transmittal, or electronic communication transmittal is considered the date of filing; if the objection is filed in person, by hand delivery or other means, the objection is filed upon receipt. Objections must be filed with the Chief Administrative Law Judge, U.S. Department of Labor, and copies of the objections must be mailed at the same time to the other parties of
record, the OSHA official who issued the findings and order, the Assistant Secretary, and the Associate Solicitor, Division of Fair Labor Standards, U.S. Department of Labor.

(b) If a timely objection is filed, all provisions of the preliminary order will be stayed, except for the portion requiring preliminary reinstatement, which will not be automatically stayed. The portion of the preliminary order requiring reinstatement will be effective immediately upon the respondent’s receipt of the findings and preliminary order, regardless of any objections to the order. The respondent may file a motion with the Office of Administrative Law Judges for a stay of the Assistant Secretary’s preliminary order of reinstatement, which shall be granted only based on exceptional circumstances. If no timely objection is filed with respect to either the findings or the preliminary order, the findings and/or the preliminary order will become the final decision of the Secretary, not subject to judicial review.

§ 1987.107 Hearings.

(a) Except as provided in this part, proceedings will be conducted in accordance with the rules of practice and procedure for administrative hearings before the Office of Administrative Law Judges, codified at subpart A of part 18 of this title.

(b) Upon receipt of an objection and request for hearing, the Chief Administrative Law Judge will promptly assign the case to an ALJ who will notify the parties, by certified mail, of the time, place of hearing. The hearing is to commence expeditiously, except upon a showing of good cause or unless otherwise agreed to by the parties. Hearings will be conducted de novo on the record. ALJs have broad discretion to limit discovery in order to expedite the hearing.

(c) If both the complainant and the respondent object to the findings and/or order, the objections will be consolidated and a single hearing will be conducted.

(d) Formal rules of evidence will not apply, but rules or principles designed to assure production of the most probative evidence will be applied. The ALJ may exclude evidence that is immaterial, irrelevant, or unduly repetitious.


(a)(1) The complainant and the respondent will be parties in every proceeding and must be served with copies of all documents in the case. At the Assistant Secretary’s discretion, the Assistant Secretary may participate as a party or as amicus curiae at any time at any stage of the proceeding. This right to participate includes, but is not limited to, the right to petition for review of a decision of an ALJ, including a decision approving or rejecting a settlement agreement between the complainant and the respondent.

(2) Parties must send copies of documents to OSHA and to the Associate Solicitor, Division of Fair Labor Standards, U.S. Department of Labor, only upon request of OSHA, or when OSHA is participating in the proceeding, or when service on OSHA and the Associate Solicitor is otherwise required by the rules in this part.

(b) The FDA, if interested in a proceeding, may participate as amicus curiae at any time in the proceeding, at the FDA’s discretion. At the request of the FDA, copies of all documents in a case must be sent to the FDA, whether or not the FDA is participating in the proceeding.

§ 1987.109 Decision and orders of the administrative law judge.

(a) The decision of the ALJ will contain appropriate findings, conclusions, and an order pertaining to the remedies provided in paragraph (d) of this section, as appropriate. A determination that a violation has occurred may be made only if the complainant has demonstrated by a preponderance of the evidence that protected activity was a contributing factor in the adverse action alleged in the complaint.

(b) If the complainant has satisfied the burden set forth in the prior paragraph, relief may not be ordered if the respondent demonstrates by clear and convincing evidence that it would have taken the same adverse action in the absence of any protected activity.

(c) Neither OSHA’s determination to dismiss a complaint without completing an investigation pursuant to § 1987.104(e) nor OSHA’s determination to proceed with an investigation is subject to review by the ALJ, and a complaint may not be remanded for the completion of an investigation or for additional findings on the basis that a determination to dismiss was made in error. Rather, if there otherwise is jurisdiction, the ALJ will hear the case on the merits or dispose of the matter without a hearing if the facts and circumstances warrant.

(d)(1) If the ALJ concludes that the respondent has violated the law, the ALJ will issue an order that will require, where appropriate: Affirmative action to abate the violation; reinstatement of the complainant to his or her former position, together with the compensation (including back pay and interest), terms, conditions, and privileges of the complainant’s employment; and payment of compensatory damages, including, at the request of the complainant, the aggregate amount of all costs and expenses (including attorney and expert witness fees) reasonably incurred.

Interest on back pay will be calculated using the interest rate applicable to underpayment of taxes under 26 U.S.C. 6621 and will be compounded daily. The order will also require the respondent to submit appropriate documentation to the Social Security Administration allocating any back pay award to the appropriate calendar quarters.

(2) If the ALJ determines that the Respondent has not violated the law, an order will be issued denying the complaint. If, upon the request of the respondent, the ALJ determines that a complaint was frivolous or was brought in bad faith, the ALJ may award to the respondent a reasonable attorney fee, not exceeding $1,000.

(e) The decision will be served upon all parties to the proceeding, the Assistant Secretary, and the Associate Solicitor, Division of Fair Labor Standards, U.S. Department of Labor. Any ALJ’s decision requiring reinstatement or lifting an order of reinstatement by the Assistant Secretary will be effective immediately upon receipt of the decision by the respondent. All other portions of the ALJ’s order will be effective 14 days after the date of the decision unless a timely petition for review has been filed with the Administrative Review Board (ARB), U.S. Department of Labor. The decision of the ALJ will become the final order of the Secretary unless a petition for review is timely filed with the ARB and the ARB accepts the petition for review.


(a) Any party desiring to seek review, including judicial review, of a decision of the ALJ, or a respondent alleging that the complaint was frivolous or brought in bad faith who seeks an award of attorney fees, must file a written petition for review with the ARB, which has been delegated the authority to act for the Secretary and issue final decisions under this part. The parties should identify in their petitions for review the legal conclusions or orders to which they object, or the objections may be deemed waived. A petition must be filed within 14 days of the date of the decision of the ALJ. The date of the
postmark, facsimile transmittal, or electronic communication transmittal will be considered to be the date of filing; if the petition is filed in person, by hand delivery or other means, the petition is considered filed upon receipt. The petition must be served on all parties and on the Chief Administrative Law Judge at the time it is filed with the ARB. Copies of the petition for review must be served on the Assistant Secretary and on the Associate Solicitor, Division of Fair Labor Standards, U.S. Department of Labor.

(b) If a timely petition for review is filed pursuant to paragraph (a) of this section, the decision of the ALJ will become the final order of the Secretary unless the ARB, within 30 days of the filing of the petition, issues an order notifying the parties that the case has been accepted for review. If a case is accepted for review, the decision of the ALJ will be inoperative unless and until the ARB issues an order adopting the decision, except that any order of reinstatement will be effective while review is conducted by the ARB, unless the ARB grants a motion by the respondent to stay that order based on exceptional circumstances. The ARB will specify the terms under which any briefs are to be filed. The ARB will review the factual determinations of the ALJ under the substantial evidence standard. If no timely petition for review is filed, or the ARB denies review, the decision of the ALJ will become the final order of the Secretary.

(c) The final decision of the ARB will be issued within 120 days of the conclusion of the hearing, which will be deemed to be 14 days after the date of the decision of the ALJ, unless a motion for reconsideration has been filed with the ALJ in the interim. In such case the conclusion of the hearing is the date the motion for reconsideration is denied or 14 days after a new decision is issued. The ARB’s final decision will be served upon all parties and the Chief Administrative Law Judge by mail. The final decision will also be served on the Assistant Secretary and on the Associate Solicitor, Division of Fair Labor Standards, U.S. Department of Labor, even if the Assistant Secretary is not a party.

(d) If the ARB concludes that the respondent has violated the law, the ARB will issue a final order providing relief to the complainant. The final order will require, where appropriate: Affirmative action to abate the violation; reinstatement of the complainant to his or her former position, together with the compensation (including back pay and interest), terms, conditions, and privileges of the complainant’s employment; and payment of compensatory damages, including, at the request of the complainant, the aggregate amount of all costs and expenses (including attorney and expert witness fees) reasonably incurred. Interest on back pay will be calculated using the interest rate applicable to underpayment of taxes under 26 U.S.C. 6621 and will be compounded daily. The order will also require the respondent to submit appropriate documentation to the Social Security Administration allocating any back pay award to the appropriate calendar quarters.

(e) If the ARB determines that the respondent has not violated the law, an order will be issued denying the complaint. If, upon the request of the respondent, the ARB determines that a complaint was frivolous or was brought in bad faith, the ARB may award to the respondent a reasonable attorney fee, not exceeding $1,000.

Subpart C—Miscellaneous Provisions

§1987.111 Withdrawal of complaints, findings, objections, and petitions for review; settlement.

(a) At any time prior to the filing of objections to the Assistant Secretary’s findings and/or preliminary order, a complainant may withdraw his or her complaint by notifying OSHA, orally or in writing, of his or her withdrawal.

(b) At any time before the Assistant Secretary’s findings and/or order become final, a party may withdraw objections to the Assistant Secretary’s findings and/or order by filing a written withdrawal with the ALJ, if the case is on review with the ARB, a party may withdraw a petition for review of an ALJ’s decision at any time before that decision becomes final by filing a written withdrawal with the ARB. The ALJ or the ARB, as the case may be, will determine whether to approve the withdrawal of the objections or the petition for review. If the ALJ approves a request to withdraw objections to the Assistant Secretary’s findings and/or order, and there are no other pending objections, the Assistant Secretary’s findings and/or order will become the final order of the Secretary. If the ARB approves a request to withdraw a petition for review of an ALJ decision, and there are no other pending petitions for review of that decision, the ALJ’s decision will become the final order of the Secretary. If objections or a petition for review are withdrawn because of settlement, the settlement must be submitted for approval in accordance with paragraph (d) of this section.

(d) (1) Investigative settlements. At any time after the filing of a complaint, but before the findings and/or order are objected to or become a final order by operation of law, the case may be settled if OSHA, the complainant, and the respondent agree to a settlement. OSHA’s approval of a settlement reached by the respondent and the complainant demonstrates OSHA’s consent and achieves the consent of all three parties.

(2) Adjudicatory settlements. At any time after the filing of objections to the Assistant Secretary’s findings and/or order, the case may be settled if the participating parties agree to a settlement and the settlement is approved by the ALJ if the case is before the ALJ, or by the ARB if the ARB has accepted the case for review. A copy of the settlement will be filed with the ALJ or the ARB, as appropriate.

(e) Any settlement approved by OSHA, the ALJ, or the ARB will constitute the final order of the Secretary and may be enforced in United States district court pursuant to §1987.113.

§1987.112 Judicial review.

(a) Within 60 days after the issuance of a final order under §§1987.109 and 1987.110, any person adversely affected or aggrieved by the order may file a petition for review of the order in the United States Court of Appeals for the circuit in which the violation allegedly occurred or the circuit in which the
complainant resided on the date of the violation.
(b) A final order is not subject to judicial review in any criminal or other civil proceeding.
(c) If a timely petition for review is filed, the record of a case, including the record of proceedings before the ALJ, will be transmitted by the ARB or the ALJ, as the case may be, to the appropriate court pursuant to the Federal Rules of Appellate Procedure and the local rules of such court.

§ 1987.113 Judicial enforcement.
Whenever any person has failed to comply with a preliminary order of reinstatement, or a final order, including one approving a settlement agreement, issued under FSMA, the Secretary may file a civil action seeking enforcement of the order in the United States district court for the district in which the violation was found to have occurred or in the United States district court for the District of Columbia. Whenever any person has failed to comply with a preliminary order of reinstatement, or a final order, including one approving a settlement agreement, issued under FSMA, a person on whose behalf the order was issued may file a civil action seeking enforcement of the order in the appropriate United States district court.

(a) The complainant may bring an action at law or equity for de novo review in the appropriate district court of the United States, which will have jurisdiction over such an action without regard to the amount in controversy, either:
(1) Within 90 days after receiving a written determination under § 1987.105(a) provided that there has been no final decision of the Secretary; or
(2) If there has been no final decision of the Secretary within 210 days of the filing of the complaint.
(b) At the request of either party, the action shall be tried by the court with a jury.
(c) A proceeding under paragraph (a) of this section shall be governed by the same legal burdens of proof specified in § 1987.109. The court shall have jurisdiction to grant all relief necessary to make the employee whole, including injunctive relief and compensatory damages, including:
(1) Reinstatement with the same seniority status that the employee would have had, but for the discharge or discrimination;
(2) The amount of back pay, with interest;
(3) Compensation for any special damages sustained as a result of the discharge or discrimination; and
(4) Litigation costs, expert witness fees, and reasonable attorney fees.
(d) Within seven days after filing a complaint in federal court, a complainant must file with OSHA, the ALJ, or the ARB, depending on where the proceeding is pending, a copy of the file-stamped complaint. In all cases, a copy of the complaint also must be served on the OSHA official who issued the findings and/or preliminary order, the Assistant Secretary, and the Associate Solicitor, Division of Fair Labor Standards, U.S. Department of Labor.

§ 1987.115 Special circumstances; waiver of rules.
In special circumstances not contemplated by the provisions of the rules in this part, or for good cause shown, the ALJ or the ARB on review may, upon application, after three days notice to all parties, waive any rule or issue such orders that justice or the administration of FSMA requires.

SUPPLEMENTARY INFORMATION:
I. Table of Abbreviations
CPR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
II. Background Information and Regulatory History
On December 7, 2015, Powerboat P1–USA, LLC notified the Coast Guard that it will conduct a series of high speed boat races in the Atlantic Ocean, offshore from Daytona Beach, FL from April 22 through 24, 2016. In response, on February 4, 2016, the Coast Guard published a notice of proposed rulemaking (NPRM) titled Special Local Regulation, Daytona Beach Grand Prix of the Seas; Atlantic Ocean, Daytona Beach, FL. RIN 1625–AA08. Following the NPRM, the Coast Guard received 3 comments. Under good cause provisions in 5 U.S.C. 553(d)(3), we are making this rule effective less than 30 days after its publication in the Federal Register. The Coast Guard finds that good cause exists for making this rule effective starting April 22, 2016 because the public was notified of this event well in advance through a proposed rule to regulate waterway activities published on February 4, 2016 [81 FR 5967]. Designated representatives will be on scene to assist the public with compliance during the nine hours per day that the regulation will be enforced.
III. Legal Authority and Need for Rule
The Coast Guard is issuing this rule under authority in 33 U.S.C. 1233. The USCG–2015–08724 Final Order, including one approving a settlement agreement, issued under authority in 33 U.S.C. 1233. The event that the regulation will be enforced.

DEPARTMENT OF HOMELAND SECURITY
Coast Guard
33 CFR Part 100
[Draft Number USCG–2015–1108]
RIN 1625–AA08
Special Local Regulation, Daytona Beach Grand Prix of the Seas; Atlantic Ocean, Daytona Beach, FL
AGENCY: Coast Guard, DHS.
ACTION: Temporary final rule.
SUMMARY: The Coast Guard is establishing a special local regulation on the waters of the Atlantic Ocean east of Daytona Beach, Florida during the Daytona Beach Grand Prix of the Seas, a series of high-speed personal watercraft boat races. This action is necessary to provide for the safety of life on the navigable waters surrounding the event. This special local regulation will be enforced daily 8 a.m. to 5 p.m., from April 22 through April 24, 2016. This rulemaking prohibits persons and vessels from being in the regulated area unless authorized by the Captain of the Port (COTP) Jacksonville or a designated representative.
DATES: This rule is effective from April 22, 2016 through April 24, 2016 and will be enforced daily from 8 a.m. to 5 p.m.
ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to http://www.regulations.gov, type USC–2015–1108 in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the link associated with this rule.
FOR FURTHER INFORMATION CONTACT: If you have questions about this rulemaking, call or email Lieutenant Allan Storm, Sector Jacksonville, Waterways Management Division, U.S. Coast Guard; telephone 904–714–7616, email Allan.H.Storm@uscg.mil.