Notice of Action

Given the outbreak and continued transmission and spread of COVID–19 within the United States and globally, I have determined that the risk of continued transmission and spread of COVID–19 between the United States and Canada poses a ''specific threat to human life or national interests.''

U.S. and Canadian officials have mutually determined that non-essential travel between the United States and Canada poses additional risk of transmission and spread of COVID–19 and places the populace of both nations at increased risk of contracting COVID–19. Moreover, given the sustained human-to-human transmission of the virus, maintaining the current level of travel between the two nations places the personnel staffing land ports of entry between the United States and Canada, as well as the individuals traveling through these ports of entry, at increased risk of exposure to COVID–19. Accordingly, and consistent with the authority granted in 19 U.S.C. 1318(b)(1)(C) and (b)(2),[4] I have determined that land ports of entry along the U.S.-Canadian border will suspend normal operations and process for entry only those travelers engaged in ''essential travel,'' defined below, for entry into the United States. Given the definition of ''essential travel'' below, this temporary alteration in land ports of entry operations should not interrupt legitimate trade between the two nations or disrupt critical supply chains that ensure food, fuel, medicine, and other critical materials reach individuals on both sides of the border.

For purposes of the temporary alteration in certain designated ports of entry operations authorized under 19 U.S.C. 1318(b)(1)(C) and (b)(2), travel through the land ports of entry and ferry terminals along the United States-Canada border shall be limited to ''essential travel,'' which includes, but is not limited to—

- U.S. citizens and lawful permanent residents returning to the United States;
- Individuals traveling for medical purposes (*e.g.,* to receive medical treatment in the United States);
- Individuals traveling to attend educational institutions;
- Individuals traveling to work in the United States (*e.g.,* individuals working in the farming or agriculture industry who must travel between the United States and Canada in furtherance of such work);
- Individuals traveling for emergency response and public health purposes (*e.g.,* government officials or emergency responders entering the United States to support Federal, state, local, tribal, or territorial government efforts to respond to COVID–19 or other emergencies);
- Individuals engaged in lawful cross-border trade (*e.g.,* truck drivers supporting the movement of cargo between the United States and Canada);
- Individuals engaged in official government travel or diplomatic travel;
- Members of the U.S. Armed Forces, and the spouses and children of members of the U.S. Armed Forces, returning to the United States; and
- Individuals engaged in military-related travel or operations.

The following travel does not fall within the definition of ''essential travel'' for purposes of this Notification—

- Individuals traveling for tourism purposes (*e.g.,* sightseeing, recreation, gambling, or attending cultural events).

At this time, this Notification does not apply to air, freight rail, or sea travel between the United States and Canada, but does apply to passenger rail and ferry travel between the United States and Canada. These restrictions are temporary in nature and shall remain in effect until 11:59 p.m. EDT on April 20, 2020. This Notification may be amended or rescinded prior to that time, based on circumstances associated with the specific threat.

The Commissioner of U.S. Customs and Border Protection (CBP) is hereby directed to prepare and distribute appropriate guidance to CBP personnel on implementation of the temporary measures set forth in this Notification. The CBP Commissioner may determine that other forms of travel, such as travel in furtherance of economic stability or social order, constitute ''essential travel'' under this Notification. Further, the CBP Commissioner may, on an individualized basis and for humanitarian reasons or for other purposes in the national interest, permit the processing of travelers to the United States not engaged in ''essential travel.''

The Acting Secretary of Homeland Security, Chad F. Wolf, having reviewed and approved this document, is delegating the authority to electronically sign this document to Chad Mizelle, who is the Acting General Counsel for DHS, for purposes of publication in the **Federal Register**.

Chad R. Mizelle,

Acting General Counsel, U.S. Department of Homeland Security.

[FR Doc. 2020–06217 Filed 3–20–20; 10:30 am]

BILLING CODE 9112–FP–P

[4] 19 U.S.C. 1318(b)(1)(C) provides that ''[n]otwithstanding any other provision of law, the Secretary of the Treasury, when necessary to respond to a national emergency declared under the National Emergencies Act (50 U.S.C. 1601 *et seq.*) or to a specific threat to human life or national interests,'' is authorized to ''take any . . . action that may be necessary to respond directly to the national emergency or specific threat.'' On March 1, 2003, certain functions of the Secretary of the Treasury were transferred to the Secretary of Homeland Security. *See* 6 U.S.C. 202(2), 203(1). Under 6 U.S.C. 212(a)(1), authorities ''related to Customs revenue functions'' were reserved to the Secretary of the Treasury. To the extent that any authority under section 1318(b)(1) was reserved to the Secretary of the Treasury, it has been delegated to the Secretary of Homeland Security. *See* Treas. Dep't Order No. 100–16 (May 15, 2003), 68 FR 28322 (May 23, 2003). Additionally, 19 U.S.C. 1318(b)(2) provides that ''[n]otwithstanding any other provision of law, the Commissioner of U.S. Customs and Border Protection, when necessary to respond to a specific threat to human life or national interests, is authorized to close temporarily any Customs office or port of entry or take any other lesser action that may be necessary to respond to the specific threat.'' Congress has vested in the Secretary of Homeland Security the ''functions of all officers, employees, and organizational units of the Department,'' including the Commissioner of CBP. 6 U.S.C. 112(a)(3).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 101, 112, 115, 117, 118, 507, and 800

[Docket No. FDA–2019–N–0011]

Office of Regulatory Affairs Division Director; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is revising chapter I of its regulations. These revisions are necessary to reflect changes to the Agency's organizational structure, including the reorganization of the Office of Regulatory Affairs. The revisions replace references to the District Director with references to the Division Director and make other related changes. The rule does not impose any new regulatory requirements on affected parties. This action is editorial in nature and is intended to improve the accuracy of the Agency's regulations.

DATES: This rule is effective March 24, 2020.

FOR FURTHER INFORMATION CONTACT: Holli Kubicki, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20852, 240–402–4557.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Office of Regulatory Affairs (ORA) has reorganized to align field activities by FDA-regulated commodity (*e.g.,* food, drugs, medical devices) or program area (*e.g.,* imports). As a result, ORA division officials now perform certain duties such as those related to administrative appeals and informal hearings previously performed by district officials. FDA regulations included numerous references to district officials. The revisions made by this rule update these references to division officials, but do not alter any substantive standards.

II. Description of the Technical Amendments

The regulations specified in this rule have been revised to replace references to the ORA district official, including ''District Director'', with references to the ORA division official, including ''Division Director'', to reflect the ORA program alignment. In addition, we have made grammatical changes and minor conforming amendments as necessary to accommodate the new terminology.

We are making these technical amendments to revise descriptions of the FDA officials designated to preside over administrative appeals and at informal hearings on appeal, among other things. The amendments are technical and editorial in nature and should not be construed as modifying any substantive standards.

III. Notice and Public Comment

Publication of this document constitutes final action of these changes under the Administrative Procedure Act (APA) (5 U.S.C. 553). Section 553 of the APA exempts ''rules of agency organization, procedure, or practice'' from proposed rulemaking (*i.e.,* notice and comment rulemaking). 5 U.S.C. 553(b)(3)(A). Rules are also exempt when an Agency finds ''good cause'' that notice and comment rulemaking procedures would be ''impracticable, unnecessary, or contrary to the public interest.'' 5 U.S.C. 553(b)(3)(B).

FDA has determined that this rulemaking meets the notice and comment exemption requirements in 5 U.S.C. 553(b)(3)(A) and (b)(3)(B). FDA's revisions relate solely to FDA's change in organizational structure and make only minor technical non-substantive changes that pertain solely to the designation of FDA officials, and do not alter any substantive standard. FDA does not believe public comment is necessary for these minor revisions.

The APA allows an effective date less than 30 days after publication as ''provided by the agency for good cause found and published with the rule'' (5 U.S.C. 553(d)(3)). A delayed effective date is unnecessary in this case because the amendments do not impose or alter any substantive requirements on affected parties. As a result, affected parties do not need time to prepare before the rule takes effect. Therefore, FDA finds good cause for the amendments to become effective on the date of publication of this action.

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 112

Dietary foods, Food grades and standards, Foods, Fruits, Incorporation by reference, Packaging and containers, Reporting and recordkeeping requirements, Safety, Vegetables.

21 CFR Part 115

Eggs and egg products, Foods.

21 CFR Part 117

Food packaging, Foods.

21 CFR Part 118

Eggs and egg products, Food grades and standards, Reporting and recordkeeping requirements.

21 CFR Part 507

Animal foods, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

21 CFR Part 800

Administrative practice and procedure, Medical devices, Ophthalmic goods and services, Packaging and containers, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Food and Drug Administration amends 21 CFR chapter I as set forth below:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for part 1 continues to read as follows:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 342, 343, 350c, 350d, 350e, 350j, 350k, 352, 355, 360b, 360ccc, 360ccc–1, 360ccc–2, 362, 371, 373, 374, 379j–31, 381, 382, 384a, 384b, 384d, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264, 271; Pub. L. 107–188, 116 Stat. 594, 668–69; Pub. L. 111–353, 124 Stat. 3885, 3889.

■ 2. Amend § 1.377 by revising the definition of ''Authorized FDA representative'' to read as follows:

§ 1.377 What definitions apply to this subpart?

* * * * *

Authorized FDA representative means an FDA Division Director in whose division the article of food involved is located or an FDA official senior to such director.

* * * * *

■ 3. In § 1.391, revise the first sentence to read as follows:

§ 1.391 Who approves a detention order?

An authorized FDA representative must approve a detention order. * * *

■ 4. Amend § 1.393 by revising paragraph (b)(12) to read as follows:

§ 1.393 What information must FDA include in the detention order?

* * * * *

(b) * * *

(12) The mailing address, telephone number, email address, fax number, and the name of the FDA Division Director in whose division the detained article of food is located;

* * * * *

■ 5. Amend § 1.402 by revising paragraph (a) introductory text to read as follows:

§ 1.402 What are the requirements for submitting an appeal?

(a) If you want to appeal a detention order, you must submit your appeal in writing to the FDA Division Director in whose division the detained article of food is located, at the mailing address, email address, or fax number identified in the detention order according to the following applicable timeframes:

* * * * *

■ 6. Amend § 1.403 by revising paragraphs (b) and (f) to read as follows:

§ 1.403 What requirements apply to an informal hearing?

* * * * *

(b) A request for a hearing under this section must be addressed to the FDA Division Director in whose division the article of food involved is located;

* * * * *

(f) Section 1.404, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart;

* * * * *

■ 7. Revise § 1.404 to read as follows:

§ 1.404 Who serves as the presiding officer for an appeal and for an informal hearing?

The presiding officer for an appeal, and for an informal hearing, must be an Office of Regulatory Affairs Program Director or another FDA official senior to an FDA Division Director.

■ 8. Amend § 1.980 by revising:
■ a. The first sentence of paragraph (c);
■ b. Paragraph (d)(3)(xi);
■ c. The first sentence of paragraph (e);
■ d. The second sentence of paragraph (g)(1);
■ e. Paragraphs (g)(3)(ii) and (iv) and (g)(4); and
■ f. Paragraphs (h)(2), (h)(3) introductory text, (h)(3)(iv), and (h)(4).

The revisions read as follows:

§ 1.980 Administrative detention of drugs.

* * * * *

(c) * * * The detention is to be for a reasonable period that may not exceed 20 calendar days after the detention order is issued, unless the FDA Division Director in whose division the drugs are located determines that a greater period is required to seize the drugs, to institute injunction proceedings, or to evaluate the need for legal action, in which case the Division Director may authorize detention for 10 additional calendar days. * * *

(d) * * *

(3) * * *

(xi) The mailing address, telephone number, and name of the FDA Division Director.

(e) * * * A detention order, before issuance, must be approved by the FDA Division Director in whose division the drugs are located. * * *

(g) * * *

(1) * * * Any appeal must be submitted in writing to the FDA Division Director in whose division the drugs are located within 5 working days of receipt of a detention order. * * *

(3) * * *

(ii) A request for a hearing under this section should be addressed to the FDA Division Director;

* * * * *

(iv) Paragraph (g)(4) of this section, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this section.

(4) The presiding officer of a regulatory hearing on an appeal of a detention order, who also must decide the appeal, must be an Office of Regulatory Affairs Program Director or another FDA official senior to an FDA Division Director who is permitted by § 16.42(a) of this chapter to preside over the hearing.

* * * * *

(h) * * *

(2) If detained drugs are not in final form for shipment, the manufacturer may move them within the establishment where they are detained to complete the work needed to put them in final form. As soon as the drugs are moved for the purpose in the preceding sentence, the individual responsible for their movement must orally notify the FDA representative who issued the detention order, or another responsible division office official, of the movement of the drugs. As soon as the drugs are put in final form, they must be segregated from other drugs, and the individual responsible for their movement must orally notify the FDA representative who issued the detention order, or another responsible division office official, of their new location. The drugs put in final form must not be moved further without FDA approval.

(3) The FDA representative who issued the detention order, or another responsible division office official, may approve, in writing, the movement of detained drugs for any of the following purposes:

* * * * *

(iv) For any other purpose that the FDA representative who issued the detention order, or other responsible division office official, believes is appropriate in the case.

(4) If an FDA representative approves the movement of detained drugs under paragraph (h)(3) of this section, the detained drugs must remain segregated from other drugs and the person responsible for their movement must immediately orally notify the official who approved the movement of the drugs, or another responsible FDA division office official, of the new location of the detained drugs.

* * * * *

PART 101—FOOD LABELING

■ 9. The authority citation for part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

■ 10. Amend § 101.17 by revising paragraphs (h)(7)(i)(A) and (E) introductory text, (h)(7)(ii)(A) through (C) introductory text, and (h)(7)(ii)(F) to read as follows:

§ 101.17 Food labeling warning, notice, and safe handling statements.

* * * * *

(h) * * *

(7) * * *

(i) * * *

(A) *Order for relabeling, diversion, or destruction under the PHS Act.* Any division office of FDA or any State or locality acting under paragraph (h)(6) of this section, upon finding shell eggs held in violation of this section, may serve upon the person in whose possession such eggs are found a written order that such eggs be relabeled with the required statement in paragraph (h)(1) of this section before further distribution. If the person chooses not to relabel, the division office of FDA or, if applicable, the appropriate State or local agency may serve upon the person a written order that such eggs be diverted (from direct consumer sale, *e.g.,* to food service) under the supervision of an officer or employee of the issuing entity, for processing in accordance with the EPIA (21 U.S.C. 1031 *et seq.*) or destroyed by or under the supervision of the issuing entity, within 10 working days from the date of receipt of the order.

* * * * *

(E) *Sale or other disposition of shell eggs under order.* After service of the order, the person in possession of the shell eggs that are the subject of the order shall not sell, distribute, or otherwise dispose of or move any eggs subject to the order unless and until the notice is withdrawn after an appeal except, after notifying FDA's division office or, if applicable, the State or local agency in writing, to:

* * * * *

(ii) * * *

(A) *Appeal of a detention order.* Any appeal shall be submitted in writing to the FDA Division Director in whose division the shell eggs are located within 5 working days of the issuance of the order. If the appeal includes a request for an informal hearing, the hearing shall be held within 5 working days after the appeal is filed or, if requested by the appellant, at a later date, which shall not be later than 20 calendar days after the issuance of the order. The order may also be appealed within the same period of 5 working days by any other person having an ownership or proprietary interest in such shell eggs. The appellant of an order shall state the ownership or proprietary interest the appellant has in the shell eggs.

(B) *Summary decision.* A request for a hearing may be denied, in whole or in part and at any time after a request for a hearing has been submitted, if the Office of Regulatory Affairs Program Director or another FDA official senior to an FDA Division Director determines that no genuine and substantial issue of fact has been raised by the material

submitted in connection with the hearing or from matters officially noticed. If the presiding FDA official determines that a hearing is not justified, written notice of the determination will be given to the parties explaining the reason for denial.

(C) *Informal hearing.* Appearance by any appellant at the hearing may be by mail or in person, with or without counsel. The informal hearing shall be conducted by an Office of Regulatory Affairs Program Director or another FDA official senior to an FDA Division Director, and a written summary of the proceedings shall be prepared by the presiding FDA official.

* * * * *

(F) *No appeal.* If there is no appeal of the order and the person in possession of the shell eggs that are subject to the order fails to relabel, divert, or destroy them within 10 working days, or if the demand is affirmed by the presiding FDA official after an appeal and the person in possession of such eggs fails to relabel, divert, or destroy them within 10 working days, the FDA division office, or, if applicable, the State or local agency may designate an officer or employee to divert or destroy such eggs. It shall be unlawful to prevent or to attempt to prevent such diversion or destruction of the shell eggs by the designated officer or employee.

* * * * *

PART 112—STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION

■ 11. The authority citation for part 112 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 342, 350h, 371; 42 U.S.C. 243, 264, 271.

■ 12. Amend § 112.202 by revising paragraph (a) to read as follows:

§ 112.202 What procedure will FDA use to withdraw an exemption?

(a) An FDA Division Director in whose division the farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to either such Director, must approve an order to withdraw the exemption before the order is issued.

* * * * *

■ 13. Amend § 112.203 by revising paragraph (h) to read as follows:

§ 112.203 What information must FDA include in an order to withdraw a qualified exemption?

* * * * *

(h) The mailing address, telephone number, email address, fax number, and name of the FDA Division Director in whose division the farm is located (or for foreign farms, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and

* * * * *

■ 14. Amend § 112.206 by revising paragraph (a)(1) to read as follows:

§ 112.206 What is the procedure for submitting an appeal?

(a) * * *

(1) Submit the appeal in writing to the FDA Division Director in whose division the farm is located (or in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, email address, or fax number identified in the order within 15 calendar days of the date of receipt of the order; and

* * * * *

■ 15. Amend § 112.208 by revising paragraph (c)(2) to read as follows:

§ 112.208 What requirements are applicable to an informal hearing?

* * * * *

(c) * * *

(2) A request for a hearing under this subpart must be addressed to the FDA Division Director (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) as provided in the order withdrawing an exemption.

* * * * *

■ 16. Revise § 112.209 to read as follows:

§ 112.209 Who is the presiding officer for an appeal and for an informal hearing?

The presiding officer for an appeal, and for an informal hearing, must be an Office of Regulatory Affairs Program Director or another FDA official senior to an FDA Division Director.

■ 17. Amend § 112.213 by revising paragraphs (a) and (b)(1) to read as follows:

§ 112.213 If my qualified exemption is withdrawn, under what circumstances would FDA reinstate my qualified exemption?

(a) If the FDA Division Director in whose division your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) determines that the farm has adequately resolved any problems with the conduct and conditions that are material to the safety of the food produced or harvested at such farm, and that continued withdrawal of the exemption is not necessary to protect the public health or prevent or mitigate a foodborne illness outbreak, the FDA Division Director in whose division your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) will, on his or her own initiative or at the request of a farm, reinstate the qualified exemption.

(b) * * *

(1) Submit a request, in writing, to the FDA Division Director in whose division your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and

* * * * *

PART 115—SHELL EGGS

■ 18. The authority citation for part 115 continues to read as follows:

Authority: 21 U.S.C. 342, 371; 42 U.S.C. 243, 264, 271.

■ 19. Amend § 115.50 by revising paragraphs (e)(1)(i) and (iii), (e)(1)(v) introductory text, (e)(2)(i) through (iii) introductory text, and (e)(2)(vi) to read as follows:

§ 115.50 Refrigeration of shell eggs held for retail distribution.

* * * * *

(e) * * *

(1) * * *

(i) *Order for diversion or destruction.* Any division office of FDA or any State or local agency acting under paragraph (d) of this section, upon finding shell eggs held in violation of this section, may serve upon the person in whose possession such eggs are found a written order that such eggs be diverted, under the supervision of an officer or employee of the issuing entity, for processing in accordance with the EPIA (21 U.S.C. 1031 *et seq.*) or destroyed by or under the supervision of said division office, within 10 working days from the date of receipt of the order.

* * * * *

(iii) *Approval of Division Director.* An order, before issuance, shall be approved by the FDA Division Director in whose division the shell eggs are located. If prior written approval is not feasible, prior oral approval shall be obtained and confirmed by written memorandum as soon as possible.

* * * * *

(v) *Sale or other disposition of shell eggs under order.* After service of the order, the person in possession of the

shell eggs that are the subject of the order shall not sell, distribute, or otherwise dispose of or move any eggs subject to the order unless and until the notice is withdrawn after an appeal except, after notifying FDA's division office or, if applicable, the State or local agency in writing, to:

* * * * *

(2) * * *

(i) *Appeal of a detention order.* Any appeal shall be submitted in writing to FDA's Division Director in whose division the shell eggs are located within 5 working days of the issuance of the order. If the appeal includes a request for an informal hearing, the hearing shall be held within 5 working days after the appeal is filed or, if requested by the appellant, at a later date, which shall not be later than 20 calendar days after the issuance of the order. The order may also be appealed within the same period of 5 working days by any other person having an ownership or proprietary interest in such shell eggs. The appellant of an order shall state the ownership or proprietary interest the appellant has in the shell eggs.

(ii) *Summary decision.* A request for a hearing may be denied, in whole or in part and at any time after a request for a hearing has been submitted, if the Office of Regulatory Affairs Program Director or another FDA official senior to an FDA Division Director determines that no genuine and substantial issue of fact has been raised by the material submitted in connection with the hearing or from matters officially noticed. If the presiding FDA official determines that a hearing is not justified, written notice of the determination will be given to the parties explaining the reason for denial.

(iii) *Informal hearing.* Appearance by any appellant at the hearing may be by mail or in person, with or without counsel. The informal hearing shall be conducted by the Office of Regulatory Affairs Program Director or another FDA official senior to an FDA Division Director, and a written summary of the proceedings shall be prepared by the presiding FDA official.

* * * * *

(vi) *No appeal.* If there is no appeal of the order and the person in possession of the shell eggs that are subject to the order fails to divert or destroy them within 10 working days, or if the demand is affirmed by the presiding FDA official after an appeal and the person in possession of such eggs fails to divert or destroy them within 10 working days, FDA's division office or appropriate State or local agency may designate an officer or employee to divert or destroy such eggs. It shall be unlawful to prevent or to attempt to prevent such diversion or destruction of the shell eggs by the designated officer or employee.

* * * * *

PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

■ 20. The authority citation for part 117 continues to read as follows:

Authority: 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

■ 21. Amend § 117.254 by revising paragraph (a) to read as follows:

§ 117.254 Issuance of an order to withdraw a qualified facility exemption.

(a) An FDA Division Director in whose division the qualified facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to either such Director, must approve an order to withdraw the exemption before the order is issued.

* * * * *

■ 22. Amend § 117.257 by revising paragraph (h) to read as follows:

§ 117.257 Contents of an order to withdraw a qualified facility exemption.

* * * * *

(h) The mailing address, telephone number, email address, fax number, and name of the FDA Division Director in whose division the facility is located (or, in the case of a foreign facility, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and

* * * * *

■ 23. Amend § 117.264 by revising paragraph (a)(1) to read as follows:

§ 117.264 Procedure for submitting an appeal.

(a) * * *

(1) Submit the appeal in writing to the FDA Division Director in whose division the facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, email address, or fax number identified in the order within 15 calendar days of the date of receipt of confirmation of the order; and

* * * * *

■ 24. Amend § 117.270 by revising paragraph (c)(2) to read as follows:

§ 117.270 Requirements applicable to an informal hearing.

* * * * *

(c) * * *

(2) A request for a hearing under this subpart must be addressed to the FDA Division Director (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) as provided in the order withdrawing an exemption.

* * * * *

■ 25. Revise § 117.274 to read as follows:

§ 117.274 Presiding officer for an appeal and for an informal hearing.

The presiding officer for an appeal, and for an informal hearing, must be an Office of Regulatory Affairs Program Director or another FDA official senior to an FDA Division Director.

■ 26. Amend § 117.287 by revising paragraphs (a) and (b)(1) to read as follows:

§ 117.287 Reinstatement of a qualified facility exemption that was withdrawn.

(a) If the FDA Division Director in whose division your facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) determines that a facility has adequately resolved any problems with the conditions and conduct that are material to the safety of the food manufactured, processed, packed, or held at the facility and that continued withdrawal of the exemption is not necessary to protect public health and prevent or mitigate a foodborne illness outbreak, the FDA Division Director in whose division your facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) will, on his or her own initiative or on the request of a facility, reinstate the exemption.

(b) * * *

(1) Submit a request, in writing, to the FDA Division Director in whose division your facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and

* * * * *

PART 118—PRODUCTION, STORAGE, AND TRANSPORTATION OF SHELL EGGS

■ 27. The authority citation for part 118 continues to read as follows:

Authority: 21 U.S.C. 321, 331–334, 342, 371, 381, 393; 42 U.S.C. 243, 264, 271.

■ 28. Amend § 118.12 by revising:

■ a. Paragraph (a)(1)(i) introductory text;

■ b. Paragraphs (a)(1)(ii) and (iv) introductory text; and

■ c. Paragraphs (a)(2)(i) through (iii) introductory text and (vi).

The revisions read as follows:

§ 118.12 Enforcement and compliance.

(a) * * *

(1) * * *

(i) *Order for diversion or destruction under the PHS Act.* Any division office of FDA or any State or locality acting under paragraph (c) of this section, upon finding shell eggs that have been produced or held in violation of this part, may serve a written order upon the person in whose possession the eggs are found requiring that the eggs be diverted, under the supervision of an officer or employee of the issuing entity, for processing in accordance with the EPIA (21 U.S.C. 1031 *et seq.*) or by a treatment that achieves at least a 5-log destruction of SE or destroyed by or under the supervision of the issuing entity, within 10 working days from the date of receipt of the order, unless, under paragraph (a)(2)(iii) of this section, a hearing is held, in which case the eggs must be diverted or destroyed consistent with the decision of the Office of Regulatory Affairs Program Director or another FDA official senior to an FDA Division Director under paragraph (a)(2)(v) of this section. The order must include the following information:

* * * * *

(ii) *Approval of Division Director.* An order, before issuance, must be approved by FDA's Division Director. If prior written approval is not feasible, prior oral approval must be obtained and confirmed by written memorandum as soon as possible.

* * * * *

(iv) *Sale or other disposition of shell eggs under order.* After service of the order, the person in possession of the shell eggs that are the subject of the order must not sell, distribute, or otherwise dispose of or move any eggs subject to the order unless and until receiving a notice that the order is withdrawn after an appeal except, after notifying FDA's division office or, if applicable, the State or local representative, in writing, to:

* * * * *

(2) * * *

(i) *Appeal of a detention order.* Any appeal must be submitted in writing to FDA's Division Director in whose division the shell eggs are located within 5 working days of the issuance of the order. If the appeal includes a request for an informal hearing, the hearing must be held within 5 working days after the appeal is filed or, if requested by the appellant, at a later date, which must not be later than 20 calendar days after the issuance of the order. The order may also be appealed within the same period of 5 working days by any other person having an ownership or proprietary interest in such shell eggs. The appellant of an order must state the ownership or proprietary interest the appellant has in the shell eggs.

(ii) *Summary decision.* A request for a hearing may be denied, in whole or in part and at any time after a request for a hearing has been submitted, if the Office of Regulatory Affairs Program Director or another FDA official senior to an FDA Division Director determines that no genuine and substantial issue of fact has been raised by the material submitted in connection with the hearing or from matters officially noticed. If the presiding FDA official determines that a hearing is not justified, written notice of the determination will be given to the parties explaining the reason for denial.

(iii) *Informal hearing.* Appearance by any appellant at the hearing may be by mail or in person, with or without counsel. The informal hearing must be conducted by the Office of Regulatory Affairs Program Director or another FDA official senior to an FDA Division Director, and a written summary of the proceedings must be prepared by the presiding FDA official.

* * * * *

(vi) *No appeal.* If there is no appeal of the order and the person in possession of the shell eggs that are subject to the order fails to divert or destroy them within 10 working days, or if the demand is affirmed by the presiding FDA official after an appeal and the person in possession of such eggs fails to divert or destroy them within 10 working days, FDA's division office or, if applicable, the State or local representative may designate an officer or employee to divert or destroy such eggs. It shall be unlawful to prevent or to attempt to prevent such diversion or destruction of the shell eggs by the designated officer or employee.

* * * * *

PART 507—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK-BASED PREVENTIVE CONTROLS FOR FOOD FOR ANIMALS

■ 29. The authority citation for part 507 continues to read as follows:

Authority: 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

■ 30. Amend § 507.62 by revising paragraph (a) to read as follows:

§ 507.62 Issuance of an order to withdraw a qualified facility exemption.

(a) An FDA Division Director in whose division the qualified facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine), or an FDA official senior to either such Director, must approve an order to withdraw the exemption before the order is issued.

* * * * *

■ 31. Amend § 507.65 by revising paragraph (h) to read as follows:

§ 507.65 Contents of an order to withdraw a qualified facility exemption.

* * * * *

(h) The mailing address, telephone number, email address, fax number, and name of the FDA Division Director in whose division the facility is located (or, in the case of a foreign facility, the same information for the Director of the Division of Compliance in the Center for Veterinary Medicine); and

* * * * *

■ 32. Amend § 507.69 by revising paragraph (a)(1) to read as follows:

§ 507.69 Procedure for submitting an appeal.

(a) * * *

(1) Submit the appeal in writing to the FDA Division Director in whose division the facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine), at the mailing address, email address, or fax number identified in the order within 15 calendar days of the date of receipt of confirmation of the order; and

* * * * *

■ 33. Amend § 507.73 by revising paragraph (c)(2) to read as follows:

§ 507.73 Requirements applicable to an informal hearing.

* * * * *

(c) * * *

(2) A request for a hearing under this subpart must be addressed to the FDA Division Director (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine) as provided in the order withdrawing an exemption.

* * * * *

■ 34. Revise § 507.75 to read as follows:

§ 507.75 Presiding officer for an appeal and for an informal hearing.

The presiding officer for an appeal, and for an informal hearing, must be an Office of Regulatory Affairs Program Director or another FDA official senior to an FDA Division Director.

■ 35. Amend § 507.85 by revising paragraphs (a) and (b)(1) to read as follows:

§ 507.85 Reinstatement of a qualified facility exemption that was withdrawn.

(a) If the FDA Division Director in whose division your facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine) determines that a facility has adequately resolved any problems with the conditions and conduct that are material to the safety of the animal food manufactured, processed, packed, or held at the facility and that continued withdrawal of the exemption is not necessary to protect public (human and animal) health and prevent or mitigate a foodborne illness outbreak, the FDA Division Director in whose division your facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine) will, on his or her own initiative or on the request of a facility, reinstate the exemption.

(b) * * *

(1) Submit a request, in writing, to the FDA Division Director in whose division your facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine); and

* * * * *

PART 800—GENERAL

■ 36. The authority citation for part 800 continues to read as follows:

Authority: 5 U.S.C. 551–559; 21 U.S.C. 301–399f.

■ 37. Amend § 800.55 by:

■ a. Revising the first sentence of paragraph (c), paragraph (d)(3)(xi), the first sentence of paragraph (e), the second sentence of paragraph (g)(1), and paragraphs (g)(3)(ii) and (iv) and (g)(4);

■ b. Adding a heading for paragraph (h); and

■ c. Revising paragraphs (h)(1), (2), and (3) introductory text, (h)(3)(iv), and (h)(4).

The revisions and addition read as follows:

§ 800.55 Administrative detention.

* * * * *

(c) * * * The detention is to be for a reasonable period that may not exceed 20 calendar days after the detention order is issued, unless the FDA Division Director in whose division the devices are located determines that a greater period is required to seize the devices, to institute injunction proceedings, or to evaluate the need for legal action, in which case the Division Director may authorize detention for 10 additional calendar days. * * *

(d) * * *

(3) * * *

(xi) The mailing address, telephone number, and name of the FDA Division Director.

(e) * * * A detention order, before issuance, shall be approved by the FDA Division Director in whose division the devices are located. * * *

(g) * * *

(1) * * * Any appeal shall be submitted in writing to the FDA Division Director in whose division the devices are located within 5 working days of receipt of a detention order.

(3) * * *

(ii) A request for a hearing under this section should be addressed to the FDA Division Director.

* * * * *

(iv) Paragraph (g)(4) of this section, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this section.

(4) The presiding officer of a regulatory hearing on an appeal of a detention order, who also shall decide the appeal, shall be an Office of Regulatory Affairs Program Director or another FDA official senior to an FDA Division Director who is permitted by § 16.42(a) of this chapter to preside over the hearing.

* * * * *

(h) *Movement of detained devices.* (1) Except as provided in this paragraph (h), no person shall move detained devices within or from the place where they have been ordered detained until FDA terminates the detention under paragraph (j) of this section or the detention period expires, whichever occurs first.

(2) If detained devices are not in final form for shipment, the manufacturer may move them within the establishment where they are detained to complete the work needed to put them in final form. As soon as the devices are moved for the purpose of the preceding sentence, the individual responsible for their movement shall orally notify the FDA representative who issued the detention order, or another responsible division office official, of the movement of the devices. As soon as the devices are put in final form, they shall be segregated from other devices, and the individual responsible for their movement shall orally notify the FDA representative who issued the detention order, or another responsible division office official, of their new location. The devices put in final form shall not be moved further without FDA approval.

(3) The FDA representative who issued the detention order, or another responsible division office official, may approve, in writing, the movement of detained devices for any of the following purposes:

* * * * *

(iv) For any other purpose that the FDA representative who issued the detention order, or other responsible division office official, believes is appropriate in the case.

(4) If an FDA representative approves the movement of detained devices under paragraph (h)(3) of this section, the detained devices shall remain segregated from other devices and the person responsible for their movement shall immediately orally notify the official who approved the movement of the devices, or another responsible FDA division office official, of the new location of the detained devices.

* * * * *

Dated: March 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–05213 Filed 3–23–20; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2019–0432; FRL–10005–66–Region 9]

Air Plan Approval; California; Santa Barbara County Air Pollution Control District; Stationary Source Permits and Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve revisions to the Santa Barbara