



4164-01-P

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-2017-N-0011]

Presiding Officer for an Appeal and Informal Hearing; 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 making revisions to Chapter I of its regulations. These revisions are necessary to reflect changes to the Agency's organizational structure, including the dissolution of the Regional Food and Drug Director position. The revisions replace references to the Regional Food and Drug Director, who is designated to preside over administrative appeals and at informal hearings on appeal, with references to Office of Regulatory Affairs Program Directors. 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 [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Peter Fox, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20852, 240-402-1857.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Office of Regulatory Affairs has dissolved the Regional Food and Drug Director position. Certain duties related to administrative appeals and informal hearings formerly held by Regional Food and Drug Directors will transfer to Office of Regulatory Affairs Program Directors. The revisions made by this rule pertain solely to the designation of FDA officials and do not alter any substantive standards.

II. Description of the Technical Amendments

The regulations specified in this rule have been revised to replace all references to the “Regional Food and Drug Director” with “Office of Regulatory Affairs Program Director,” to reflect the change in designation. In addition, the regulations have been revised to authorize other FDA officials senior to an FDA District Director to perform duties related to administrative appeals and informal hearings. Finally, we have made minor conforming amendments and grammatical changes as necessary to accommodate the new language.

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. The rule does not impose any new regulatory requirements on affected parties. The amendments are editorial in nature and should not be construed as modifying any substantive standards or requirements.

III. Notice and Public Comment

Publication of this document constitutes final action of these changes under the Administrative Procedure Act (5 U.S.C. 553). Section 553 of the Administrative Procedure Act (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 make technical or 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 any new regulatory 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, 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.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1, 101, 112, 115, 117, 118, 507, and 800 are amended as follows:

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 § 1.403 by revising paragraph (f) to read as follows:

§ 1.403 What requirements apply to an informal hearing?

* * * * *

(f) Section 1.404, rather than § 16.42(a) of this chapter, describes the FDA employees, i.e., Office of Regulatory Affairs Program Directors or other officials senior to a District Director, who preside at hearings under this subpart;

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3. 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 District Director.

4. Amend § 1.980 by revising paragraphs (g)(3)(iv) and (g)(4) to read as follows:

§ 1.980 Administrative detention of drugs.

* * * * *

(g) * * *

(3) * * *

(iv) Paragraph (g)(4) of this section, rather than § 16.42(a) of this chapter, describes the FDA employees, i.e., Office of Regulatory Affairs Program Directors or other FDA officials senior to an FDA District Director, 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 District Director who is permitted by § 16.42(a) of this chapter to preside over the hearing.

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PART 101--FOOD LABELING

5. 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.

6. Amend § 101.17 by revising paragraphs (h)(7)(ii) introductory text, (h)(7)(ii)(B), (h)(7)(ii)(C) introductory text, (h)(7)(ii)(C)(1), (h)(7)(ii)(C)(4), (h)(7)(ii)(C)(5), (h)(7)(ii)(C)(6), (h)(7)(ii)(D), (h)(7)(ii)(E), and (h)(7)(ii)(F) to read as follows:

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

* * * * *

(h) * * *

(7) * * *

(ii) The person on whom the order for relabeling, diversion, or destruction is served may either comply with the order or appeal the order to an Office of Regulatory Affairs Program Director.

* * * * *

(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 District 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 District Director, and a written summary of the proceedings shall be prepared by the presiding FDA official.

(1) The presiding FDA official may direct that the hearing be conducted in any suitable manner permitted by law and this section. The presiding FDA official has the power to take such actions and make such rulings as are necessary or appropriate to maintain order and to conduct an informal, fair, expeditious, and impartial hearing, and to enforce the requirements concerning the conduct of hearings.

* * * * *

(4) The party requesting the hearing may have the hearing transcribed, at the party's expense, in which case a copy of the transcript is to be furnished to FDA. Any transcript of the hearing will be included with the presiding FDA official's report of the hearing.

(5) The presiding FDA official shall prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. Whenever time permits, the presiding FDA official may give the parties the opportunity to review and comment on the report of the hearing.

(6) The presiding FDA official shall include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and shall include a recommended decision, with a statement of reasons.

(D) Written appeal. If the appellant appeals the detention order but does not request a hearing, the presiding FDA official shall render a decision on the appeal affirming or revoking the detention within 5-working days after the receipt of the appeal.

(E) Presiding FDA official's decision. If, based on the evidence presented at the hearing or by the appellant in a written appeal, the presiding FDA official finds that the shell eggs were held in violation of this section, he shall affirm the order that they be relabeled, diverted under the supervision of an officer or employee of FDA for processing under the EPIA, or destroyed by or under the supervision of an officer or employee of FDA; otherwise, the presiding FDA official shall issue a written notice that the prior order is withdrawn. If the presiding FDA official affirms the order, he shall order that the relabeling, diversion, or destruction be accomplished within 10-working days from the date of the issuance of his decision. The presiding FDA official's decision shall be accompanied by a statement of the reasons for the decision. The decision of the presiding FDA official shall constitute final agency action, reviewable in the courts.

(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 district 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.

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

7. 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.

8. 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 District Director.

PART 115--SHELL EGGS

9. 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.

10. Amend § 115.50 by revising paragraphs (e)(2) introductory text, (e)(2)(ii), (e)(2)(iii) introductory text, (e)(2)(iii)(A), (e)(2)(iii)(D), (e)(2)(iii)(E), (e)(2)(iii)(F), (e)(2)(iv), (e)(2)(v), and (e)(2)(vi) to read as follows:

§ 115.50 Refrigeration of shell eggs held for retail distribution.

* * * * *

(e) * * *

(2) The person on whom the order for diversion or destruction is served may either comply with the order or appeal the order to an Office of Regulatory Affairs Program Director in accordance with the following procedures:

* * * * *

(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 District 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 District Director, and a written summary of the proceedings shall be prepared by the presiding FDA official.

(A) The presiding FDA official may direct that the hearing be conducted in any suitable manner permitted by law and this section. The presiding FDA official has the power to take such actions and make such rulings as are necessary or appropriate to maintain order and to conduct an informal, fair, expeditious, and impartial hearing, and to enforce the requirements concerning the conduct of hearings.

* * * * *

(D) The party requesting the hearing may have the hearing transcribed, at the party's expense, in which case a copy of the transcript is to be furnished to FDA. Any transcript of the hearing will be included with the presiding FDA official's report of the hearing.

(E) The presiding FDA official shall prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. Whenever time permits, the presiding FDA official may give the parties the opportunity to review and comment on the report of the hearing.

(F) The presiding FDA official shall include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and shall include a recommended decision, with a statement of reasons.

(iv) Written appeal. If the appellant appeals the detention order but does not request a hearing, the presiding FDA official shall render a decision on the appeal affirming or revoking the detention within 5-working days after the receipt of the appeal.

(v) Presiding FDA official's decision. If, based on the evidence presented at the hearing or by the appellant in a written appeal, the presiding FDA official finds that the shell eggs were held in violation of this section, he shall affirm the order that they be diverted, under the supervision of an officer or employee of FDA for processing under the EPIA or destroyed by or under the supervision of an officer or employee of FDA; otherwise, the presiding FDA official shall issue a written notice that the prior order is withdrawn. If the presiding FDA official affirms the order, he shall order that the diversion or destruction be accomplished within 10-working days from the date of the issuance of his decision. The presiding FDA official's decision shall be accompanied by a statement of the reasons for the decision. The decision of the presiding FDA official shall constitute final agency action, reviewable in the courts.

(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 district 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.

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

11. 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.

12. 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 District Director.

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

13. 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.

14. Amend § 118.12 by revising paragraphs (a)(1)(i) introductory text, (a)(2) introductory text, (a)(2)(ii), (a)(2)(iii) introductory text, (a)(2)(iii)(A), (a)(2)(iii)(D), (a)(2)(iii)(E), (a)(2)(iii)(F), (a)(2)(iv), (a)(2)(v), and (a)(2)(vi) to read as follows:

§ 118.12 Enforcement and compliance.

(a) * * *

(1) * * *

(i) Order for diversion or destruction under the PHS Act. Any district 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 regulation, 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 District Director under paragraph (a)(2)(v) of this section. The order must include the following information:

* * * * *

(2) The person on whom the order for diversion or destruction is served may either comply with the order or appeal the order to an Office of Regulatory Affairs Program Director in accordance with the following procedures:

* * * * *

(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 District 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 District Director, and a written summary of the proceedings must be prepared by the presiding FDA official.

(A) The presiding FDA official may direct that the hearing be conducted in any suitable manner permitted by law and by this section. The presiding FDA official has the power to take such actions and make such rulings as are necessary or appropriate to maintain order and to

conduct an informal, fair, expeditious, and impartial hearing, and to enforce the requirements concerning the conduct of hearings.

* * * * *

(D) The party requesting the hearing may have the hearing transcribed, at the party's expense, in which case a copy of the transcript is to be furnished to FDA. Any transcript of the hearing will be included with the presiding FDA official's report of the hearing.

(E) The presiding FDA official must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. Whenever time permits, the presiding FDA official may give the parties the opportunity to review and comment on the report of the hearing.

(F) The presiding FDA official must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a recommended decision, with a statement of reasons.

(iv) Written appeal. If the appellant appeals the detention order but does not request a hearing, the presiding FDA official must render a decision on the appeal affirming or revoking the detention order within 5-working days after the receipt of the appeal.

(v) Presiding FDA official's decision. If, based on the evidence presented at the hearing or by the appellant in a written appeal, the presiding FDA official finds that the shell eggs were produced or held in violation of this section, he must affirm the order that they be diverted, under the supervision of an officer or employee of FDA for processing under the EPIA or by a treatment that achieves at least a 5-log destruction of SE or destroyed by or under the supervision of an officer or employee of FDA; otherwise, the presiding FDA official must issue a written notice that the prior order is withdrawn. If the presiding FDA official affirms the order, he must

order that the diversion or destruction be accomplished within 10-working days from the date of the issuance of his decision. The presiding FDA official's decision must be accompanied by a statement of the reasons for the decision. The decision of the presiding FDA official constitutes final agency action, subject to judicial review.

(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 district 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.

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

15. 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.

16. 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 District Director.

PART 800--GENERAL

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

Authority: 21 U.S.C. 321, 334, 351, 352, 355, 360e, 360i, 360k, 361, 362, 371.

18. Amend § 800.55 by revising paragraphs (g)(3)(iv) and (g)(4) to read as follows:

§ 800.55 Administrative detention.

* * * * *

(g) * * *

(3) * * *

(iv) Paragraph (g)(4) of this section, rather than § 16.42(a) of this chapter, describes the FDA employees, i.e., Office of Regulatory Affairs Program Directors or other FDA officials senior to an FDA District Director, 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 District Director who is permitted by § 16.42(a) of this chapter to preside over the hearing.

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Dated: March 13, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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