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authorized to require a manufacturer of a device to conduct postmarket surveillance if the official determines that postmarket surveillance of the device is necessary to protect the public health or provide safety or effectiveness data for the device:

(1) The Director and Deputy Directors, CDRH.

(2) The Director and Deputy Director, Office of Surveillance and Biometrics, CDRH.

(3) The Director and Deputy Director, Division of Postmarket Surveillance, Office of Surveillance and Biometrics, CDRH.

(4) The Director and Deputy Directors, Office of Device Evaluation, CDRH.

(5) The Director and Deputy Director, Office of Compliance, CDRH.

(6) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(7) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(8) The Director and Deputy Director, Office of Compliance, CDER.

(9) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(10) The Director and Deputy Director, Office of Compliance, CBER.

(11) The Director and Deputy Director, Office of Biological Product Review, CBER.

[57 FR 40315, Sept. 3, 1992, as amended at 62 FR 2556, Jan. 17, 1997; 62 FR 67272, Dec. 24, 1997]

§5.61 Food standards, food additives, generally recognized as safe (GRAS) substances, color additives, nutrient content claims, and health claims.

(a)(1) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 409 and 721 of the Federal Food, Drug, and Cosmetic Act (the act) regarding the issuance of notices of filing (including notices of extension of, or reopening of, the comment period), and of voluntary withdrawal, of petitions on food additives, generally recognized as safe (GRAS) substances, and color additives that relate to the as-

signed functions of the respective Center:

(i) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN).

(ii) The Director, Office of Policy, Planning and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Pre-market Approval, CFSAN.

(iv) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(2) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN), and the Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN are authorized to perform all the functions of the Commissioner of Food and Drugs under section 401 of the act regarding the issuance of proposed rulemaking (including notices of extension of, or reopening of, the comment period) pertaining to food standards.

(b)(1) The Director and Deputy Directors, CFSAN, and the Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN are authorized to perform all of the functions of the Commissioner of Food and Drugs under sections 409 and 721 of the act regarding the approval of the use of food additives under section 409(e) of the act and the listing of color additives under section 721(d) of the act where the listing does not involve novel or controversial issues and does not involve any questions about the applicability of the Delaney Anti-Cancer Clause.

(2) The following officials are authorized to perform all of the functions of the Commissioner of Food and Drugs under section 401 of the act regarding the issuance of notices of temporary permits for foods varying from standards of identity under §130.17 of this chapter:

(i) The Director and Deputy Directors, CFSAN.

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Food Labeling, CFSAN.

(3) The Director and Deputy Director, CVM, are authorized to perform all the functions of the Commissioner of Food and Drugs regarding approvals of the

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use of food additives under section 409(e) of the act, where these approvals do not involve novel or controversial issues, including any question about the applicability of the Delaney Anti-Cancer Clause.

(c)(1) The following officials are authorized to issue 90-day letters to food additive petitioners under section 409(c)(2) of the act or to color additive petitions under section 721(d)(1) of the act that relate to the assigned functions of the Center:

(i) The Director and Deputy Directors, CFSAN.

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Pre-market Approval, CFSAN.

(iv) The Director, Division of Product Policy, Office of Pre-market Approval, CFSAN.

(v) The Director, Division of Petition Control, Office of Pre-market Approval, CFSAN.

(2) The following officials are authorized to issue 90-day letters to food additive petitioners under section 409(c)(2) of the act that relate to the assigned functions of the Center:

(i) The Director and Deputy Director, CVM.

(ii) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(iii) The Director and Deputy Director, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(d) The following officials are authorized to certify batches of color additives under section 721 of the act:

(1) The Director and Deputy Directors, CFSAN.

(2) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(3) The Director, Office of Cosmetics and Colors, CFSAN.

(e) The following officials are authorized to issue advance notices of proposed rulemaking pertaining to Codex Alimentarius food standards and notices terminating consideration of such standards when comments fail to support the desirability and need for proposing their adoption, under §130.6 of this chapter:

(1) The Director and Deputy Directors, CFSAN.

(2) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(3) The Director, Office of Food Labeling, CFSAN.

(f) The following officials are authorized to issue notices of proposed rulemaking and issue or amend regulations affirming generally recognized as safe (GRAS) status of food substances under §170.35 or §570.35 of this chapter where the affirmations relate to the assigned functions of the respective Center and do not involve novel or controversial issues:

(1) The Director and Deputy Directors, CFSAN, and the Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(2) The Director and Deputy Director, CVM.

(g)(1) The following officials are authorized to perform all of the functions of the Commissioner of Food and Drugs under section 403(r)(4) of the act regarding the issuance of decisions to grant or deny petitions for nutrient content claims and health claims that do not present controversial issues and regarding the issuance of any notices of proposed rulemaking that result from such action:

(i) The Director and Deputy Directors, CFSAN.

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(2) The following officials are authorized to perform all of the functions of the Commissioner of Food and Drugs under section 403(r)(4) of the act regarding the issuing of letters of filing in response to petitions for nutrient content claims and health claims:

(i) The Director and Deputy Directors, CFSAN.

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Food Labeling, CFSAN.

(h) The following officials are authorized to issue letters concerning substances determined to be below the “threshold of regulation” under §170.39 of this chapter:

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(1) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN).

(2) The Director, Office of Policy, Planning and Strategic Initiatives, CFSAN.

(3) The Director, Office of Premarket Approval, CFSAN.

(4) The Directors of the Divisions of Petition Control and Product Policy, Office of Premarket Approval, CFSAN.

(i) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 409(h) of the act, excluding the duties set out in section 409(h)(5) of the act, regarding premarket notification of food-contact substances:

(1) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN).

(2) The Director, Office of Regulations and Policy, CFSAN.

(3) The Director, Office of Premarket Approval, CFSAN.

[49 FR 14936, Apr. 16, 1984, as amended at 49 FR 48183, Dec. 11, 1984; 52 FR 5951, Feb. 27, 1987; 58 FR 2410, Jan. 6, 1993; 59 FR 42492, Aug. 18, 1994; 60 FR 36594, July 17, 1995; 64 FR 33194, June 22, 1999]

§5.62 Issuance of initial emergency permit orders and notices of confirmation of effective date of final regulations on food for human and animal consumption.

(a) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN), the Director, Office of Field Programs, CFSAN, and the Director, Division of Enforcement, Office of Field Programs, CFSAN, are authorized to issue initial emergency permit orders under §108.5 of this chapter.

(b) The following officials are authorized to issue notices of confirmation of effective date of final regulations on food matters promulgated under section 701(e) of the Federal Food, Drug, and Cosmetic Act:

(1) The Director and Deputy Directors, CFSAN.

(2) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(3) The Director, Office of Food Labeling, CFSAN.

(4) The Director, Office of Special Nutritionals, CFSAN.

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(5) The Director, Office of Plant and Dairy Foods and Beverages, CFSAN.

(6) The Director, Office of Seafood, CFSAN.

(7) The Director, Office of Field Programs, CFSAN.

(8) The Director, Office of Premarket Approval, CFSAN.

[59 FR 42492, Aug. 18, 1994]

§5.63 Detention of meat, poultry, eggs, and related products.

The Regional Food and Drug Directors and District Directors are authorized to perform and to designate other officials to perform all of the functions of the Commissioner of Food and Drugs under:

(a) Section 409(b) of the Federal Meat Inspection Act (21 U.S.C. 679(b)) which relate to the detention of any carcass, part thereof, meat, or meat product of cattle, sheep, swine, goats, or equines.

(b) Section 24(b) of the Poultry Products Inspection Act (21 U.S.C. 467f(b)) which relate to the detention of any poultry carcass, part thereof, or poultry product.

(c) The Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

[48 FR 8442, Mar. 1, 1983, as amended at 54 FR 9034, Mar. 3, 1989; 60 FR 15871, Mar. 28, 1995]

§5.64 Establishing standards and approving accrediting bodies under the National Laboratory Accreditation Program.

The Director and Deputy Director, Center for Food Safety and Applied Nutrition, are authorized to perform all the functions of the Commissioner of Food and Drugs under sections 1322(b) and (c) of the Food, Agriculture, Conservation, and Trade Act of 1990 (the National Laboratory Accreditation Program) (7 U.S.C. 138a), as amended hereafter; which relate to setting standards for the National Laboratory Accreditation Program and approving State agencies or private, nonprofit entities as accrediting bodies to implement certification and quality assurance programs in accordance with the requirements of these sections. The delegation excludes the authority to submit reports to the Congress.

[57 FR 43398, Sept. 21, 1992]