SMG 1410.301

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - FOOD AND COSMETICS

FOOD STANDARDS, FOOD ADDITIVES, GENERALLY RECOGNIZED AS SAFE (GRAS) SUBSTANCES, COLOR ADDITIVES, NUTRIENT CONTENT CLAIMS, AND HEALTH CLAIMS

Effective Date: 06/02/2006

1. AUTHORITIES DELEGATED AND TO WHOM DELEGATED.

A.1. The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) under sections 409 and 721 of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 348 and 379e) 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 assigned functions of the respective Center:

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

b. The Director of Regulations and Policy (CFSAN).

c. Director and Deputy Director, Office of Food Additive Safety, OFAS, (CFSAN).

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

2. The Director, Deputy Director, and Director of Regulations and Policy, CFSAN are authorized to perform all the functions of the Commissioner under section 401 of the act (21 U.S.C. 341) 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, Deputy Director, and Director of Regulations and Policy, CFSAN are authorized to perform all of the functions of the Commissioner under section 409 and 721 of the act (21 U.S.C. 348 and 379e) regarding the approval of the use of food additives under section 409(e) of the act (21 U.S.C. 348(e)) and the listing of color additives under section 721(d)(1) of the act (21 U.S.C. 379e) 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 under section 401 of the act (21 U.S.C. 341) regarding the issuance of notices of temporary permits for foods varying from standards of identity under 21 CFR, Part 100, section 130.17:

    a. The Director and Deputy Director, CFSAN.

    b. The Director of Regulations and Policy, CFSAN.

    c. The Director, Office of Nutritional Products, Labeling, and Dietary Supplements, CFSAN.

3. The Director and Deputy Director, CVM, are authorized to perform all the functions of the Commissioner regarding approvals of the use of food additives under section 409(e) of the act (21 U.S.C. 348(e)), 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 (21 U.S.C. 348(c)(2)) or to color additive petitions under section 721e(d)(1) (21 U.S.C. 379e(d)(1)) of the act that relate to the assigned functions of the Center:

    a. The Director and Deputy Director, CFSAN.

    b. The Director of Regulations and Policy, CFSAN.

    c. Director and Deputy Director, Office of Food Additive Safety, OFAS, CFSAN.

    d. Director, Division of Petition Review, OFAS, CFSAN.

    e. Director, Division of Food Contact Substance Notification Review, OFAS, CFSAN.

    f. Director, Division of Biotechnology and GRAS Notice Review, OFAS, CFSAN.

2. The following officials are authorized to issue 90-day letters to food additive petitioners under section 409(c)(2) of the act (21 U.S.C. 348(c)(2)) that relate to the assigned functions of the Center:

a. The Director and Deputy Director, CVM.

b. The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

c. 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 (21 U.S.C. 379e):

1. The Director and Deputy Director, CFSAN.

2. The Director of Regulations and Policy, 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 21 CFR, Part 100, section 130.6:

1. The Director and Deputy Director, CFSAN.

2. The Director of Regulations and Policy, CFSAN.

3. The Director, Office of Nutritional Products, Labeling, and Dietary Supplements, CFSAN.

F. The following officials are authorized to issue notices of proposed rulemaking and issue or amend regulations affirming GRAS status of food substances under 21 CFR, Parts 100 or 500, sections 170.35 or 570.35 where the affirmations relate to the assigned functions of the respective Center and do not involve novel or controversial issues:

1. The Director, Deputy Director, and Director of Regulations and Policy, CFSAN.

2. The Director and Deputy Director, CVM.

G.1. The following officials are authorized to perform all of the functions of the Commissioner regarding the issuance of decisions related to nutrient content claims and health claims under section 403(r)(4) of the act (21 U.S.C. 343(r)(4)):

a. The Director and Deputy Director, CFSAN.

b. The Deputy Director for Regulatory Affairs, CFSAN.

c. The Director, Office of Nutritional Products, Labeling, and Dietary Supplements, CFSAN.

2. The following officials are authorized to perform all of the functions of the Commissioner regarding the issuance of any notices of proposed rulemaking under section 403(r)(4) of the act (21 U.S.C. 343(r)(4)):

a. The Director and Deputy Director, CFSAN.

b. The Deputy Director for Regulatory Affairs, CFSAN.

H. The following officials are authorized to issue letters concerning substances determined to be below the "threshold of regulation" under 21 CFR, Part 100, section 170.39:

1. The Director and Deputy Director, CFSAN.

2. The Director of Regulations and Policy, CFSAN.

3. The Director and Deputy Director, OFAS, CFSAN.

4. The Director, Division of Food Contact Substance Notification Review. OFAS CFSAN.

I. The following officials are authorized to perform all of the functions of the Commissioner under section 409(h) of the act (21 U.S.C. 348(h)), excluding the duties to set out in section 409(h)(5) of the act (21 U.S.C. 348(h)(5)), regarding premarket notification of food-contact substances:

1. The Director and Deputy Director, CFSAN.

2. The Director of Regulations and Policy, CFSAN.

3. The Director and Deputy Director, Office of Food Additive Safety, CFSAN.

J. The following officials are authorized to perform all of the functions of the Commissioner regarding the issuance of responses to petitions submitted under section 403(w)(6) and the issuance of objections to notifications filed under section 403(w)(7) of the act (21 U.S.C. 343(w)(6) and (w)(7)):

1. The Director and Deputy Director, CFSAN.

2. The Deputy Director for Regulatory Affairs, CFSAN.

3. The Director, Office of Food Additive Safety, CFSAN.

4. The Director, Office of Nutritional Products, Labeling, and Dietary Supplements, CFSAN.

2. REDELEGATION.

These officials may not further redelegate these authorities.

3. EFFECTIVE DATE.

This delegation was signed by Andrew C. von Eschenbach, M.D., Acting Commissioner of Food and Drugs, and became effective on June 2, 2006.