SMG 1410.30

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - GENERAL REDELEGATIONS OF AUTHORITY

PETITIONS UNDER TITLE 21, CODE OF FEDERAL REGULATIONS (21 CFR), PART 10

Effective Date: September 2, 2015

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

A. The following officials are authorized to grant or deny citizen petitions submitted under 21 CFR,10.30, requesting in vitro test modifications under 21 CFR 331.21.

1. Director and Deputy Directors, Center for Drug Evaluation and Research (CDER), Office of Medical Products and Tobacco (OMPT).

2. Directors, Office of New Drugs (OND), Office of Generic Drugs (OGD), and Office of Pharmaceutical Quality (OPQ), CDER, OMPT.

3. Director, Office of Drug Evaluation (ODE) IV, OND, CDER, OMPT.

B. The following officials are authorized to grant or deny citizen petitions, in whole or in part, submitted under 21 CFR 10.30 for a stay of an effective date or for an exemption from the tamper-resistant packaging and labeling requirements set forth in 21 CFR 211.132, 700.25, or 800.12, for certain over-the-counter human drug and cosmetic products and medical devices which relate to the assigned functions of the respective organizations:

1. Director and Deputy Directors, CDER, OMPT.

2. Directors, OND, OGD, and OPQ, CDER, OMPT.

3. Director, Office of Drug Evaluation (ODE) IV, OND, CDER, OMPT.

4. Director, Deputy Director for Regulatory Affairs and Deputy Director for Scientific Operations, Center for Food Safety and Applied Nutrition (CFSAN), Office of Foods and Veterinary Medicine (OFVM).

5. Director and Deputy Director, Office of Cosmetics and Colors (OCAC), CFSAN, OFVM.

6. Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), OMPT.

C. The following officials are authorized to grant or deny citizen petitions submitted under 21 CFR 10.30, requesting exemption from the general pregnancy-nursing warning for over-the-counter (OTC) drugs required under 21 CFR 201.63, requesting exemption from a general overdose warning required under 21 CFR 330.1(g) and requesting amendment or repeal of any final monograph established under the procedures described in 21 CFR 330.10:

1. Director and Deputy Directors, CDER, OMPT

2. Directors, OND, OGD and OPQ, CDER, OMPT.

3. Director, ODE IV, OND, CDER, OMPT.

D. The following officials are authorized to issue 180-day tentative responses to citizen petitions on food and cosmetic matters under 21 CFR 10.30(e)(2)(iii), that relate to the assigned functions of that Center:

1. Director, Deputy Director for Regulatory Affairs, and Deputy Director for Scientific Operations, CFSAN, OFVM.

2. Director and Deputy Director, OCAC, CFSAN, OFVM.

3. Director, Office of Nutrition, Labeling, and Dietary Supplements ONLDS), CFSAN, OFVM.

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

5. Director and Deputy Director, Office of Food Safety (OFS), CFSAN, OFVM.

6. Director, Office of Compliance, (OC) CFSAN, OFVM.

E. The following officials are authorized to issue 180-day tentative responses to citizen petitions on animal food and drug matters under 21 CFR 10.30(e)(2)(iii), that relate to the assigned functions of that Center:

1. Director and Deputy Directors, Center for Veterinary Medicine (CVM), OFVM.

F. The following officials are authorized to issue 180-day tentative responses to citizen petitions on biological product matters under 21 CFR 10.30(e)(2)(iii), that relate to the assigned functions of that Center:

1. Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), OMPT.

2. Director and Deputy Directors, CDER, OMPT.

3. Director and Deputy Director, Office of Regulatory Policy (ORP), CDER, OMPT.

G. The following officials are authorized to issue 180-day tentative responses to citizen petitions on drug product matters under 21 CFR 10.30(e)(2)(iii), that relate to the assigned functions of that Center:

1. Director and Deputy Director, CBER, OMPT.

2. Director, Deputy Directors, CDER, OMPT.

3. Director and Deputy Director, ORP, CDER, OMPT.

H. The following officials are authorized to issue 180-day tentative responses to citizen petitions on medical device matters under 21 CFR 10.30(e)(2)(iii) that relate to the assigned functions of that Center:

1. Director and Deputy Directors, CDRH, OMPT.

I. The following officials are authorized to issue 180-day tentative responses to citizen petitions on tobacco product matters under 21 CFR 10.30(e)(2)(iii), that relate to the assigned functions of that Center:

1. Director and Deputy Director, Center for Tobacco Products (CTP), OMPT.

2. Director, Office of Regulations, CTP, OMPT.

J. The following officials are authorized to grant or deny citizen petitions submitted under 21 CFR 10.30, and petitions for administrative stays of action submitted under 21 CFR 10.35, on drug and biological product matters (including inspection issues) in program areas where they have been delegated final approval authority as referenced in the following SMGs: SMG 1410.102 Termination of exemptions for new drugs for investigational use in human beings or in animals; SMG 1410.104 Approval of new drug applications and their supplements; SMG 1410.106 Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements; SMG 1410.204 Issuance and revocation of licenses for the propagation or manufacture and preparation of biological products; SMG 1410.205 Notification of release for distribution of biological products.

1. Director and Deputy Director, CBER, OMPT.

2. Director and Deputy Directors, CDER, OMPT.

3. Directors, OND, OGD, and OPQ, CDER, OMPT.

K. The following officials are authorized to grant or deny citizen petitions submitted under 21 CFR 10.30 and petitions for stay of action submitted under 21 CFR 10.35, on drug product matters (including inspection issues) in program areas where they have been delegated final approval authority as referenced in the following SMGs: SMG 1410.35 Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment; SMG 1410.101 Issuance of notices implementing the provisions of the Drug Amendments of 1962.

1. Director and Deputy Directors, CDER, OMPT.

2. Directors, OND, OGD, and OPQ, CDER, OMPT.

L. The following officials, except for those drug products listed in 21 CFR 314.440(b), are authorized to issue responses to citizen petitions submitted under 21 CFR10.30 seeking a determination of the suitability of an abbreviated new drug application for a drug product:

1. Director and Deputy Director, OGD, CDER, OMPT.

M. For those drug products listed in 21 CFR 314.440(b), the following officials are authorized to issue responses to citizen petitions submitted under 21 CFR10.30, seeking a determination of the suitability of an abbreviated new drug application for a drug product:

1. Directors and Deputy Directors, Office of Blood, Research, Review (OBRR), Office of Vaccines Research and Review (OVRR), and Office of Cellular, Tissue, and Gene Therapies (OCTGT), CBER, OMPT.

N. For drugs assigned to their organization, the following officials are authorized to issue responses to citizen petitions submitted under 21 CFR, 10.30, and petitions for administrative stays of action submitted under 21 CFR 10.35, from sponsors of an investigational new drug application who request approval to ship in interstate commerce:

1. Director and Deputy Director, CBER, OMPT.

2. Director and Deputy Directors, CDER, OMPT.

3. Directors, OND, OGD and OPQ, CDER, OMPT.

O. The following officials are authorized to issue responses to citizen petitions submitted under 21 CFR 10.30, and petitions for administrative stays of action submitted under 21 CFR 10.35, from sponsors of an investigational new animal

drug application who request approval to ship in interstate commerce, in accordance with 21 CFR 2.125, an investigational new animal drug for animal use containing a chlorofluorocarbon:

1. Director and Deputy Directors, Center for Veterinary Medicine (CVM), OFVM.

P. The following officials are authorized to issue responses to citizen petitions submitted under 21 CFR 10.30, and petitions for administrative stays of action submitted under 21 CFR 10.35, seeking a determination of the suitability of an abbreviated new animal drug application for an animal drug product:

1. Director and Deputy Director, Office of New Animal Drug Evaluation, CVM, OFVM.

Q. The following officials are authorized to grant or deny citizen petitions submitted under 21 CFR 10.30, and petitions for administrative stays of action submitted under 21 CFR 10.35, concerning actions where they have been delegated authority as referenced in SMG 1410.35 Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment:

1. Director and Deputy Directors, CVM, OFVM.

R. The following officials are authorized to grant or deny citizen petitions submitted under 21 CFR 10.30 and 821.2(b), requesting an exemption or variance from medical device tracking requirements in 21 CFR Part 821:

1. Director and Deputy Directors, CDRH, OMPT.

2. Director, Office of Compliance, CDRH, OMPT.

S. The following officials are authorized to grant or deny citizen petitions, in whole or in part, submitted under 21 CFR 10.30, and petitions for administrative stays of action submitted under 21 CFR 10.35 that pertain exclusively to human food and cosmetic matters that relate to the assigned functions of that Center:

1. Director, Deputy Director for Regulatory Affairs, and Deputy Director for Scientific Operations, CFSAN, OFVM.

2. Director and Deputy Director, OCAC, CFSAN, OFVM.

3. Director and Deputy Director, ONLDS, CFSAN, OFVM.

4. Director and Deputy Director, OFAS, CFSAN, OFVM.

5. Director and Deputy Director, OFS, CFSAN, OFVM.

6. Director and Deputy Director, OC, CFSAN, OFVM.

T. The following officials are authorized to grant and deny petitions submitted under 21 CFR 10.30 and 10.35 on medical device, electronic product radiation control, and mammography that relate to the assigned functions of that Center:

1. Director and Deputy Directors, CDRH, OMPT.

U. The following officials are authorized to grant or deny citizen petitions submitted under 21 CFR 10.30, that pertain exclusively to tobacco product matters that relate to the assigned functions of that Center:

1. Director and Deputy Director, CTP,OMPT.

2. Director, Office of Regulations, CTP, OMPT.

V. The following officials are authorized to grant or deny citizen petitions, in whole or in part, submitted under 21 CFR 10.30, that pertain exclusively to matters that relate to the assigned functions of that Center:

1. Director and Deputy Directors, CVM, OFVM.

2. RE-DELEGATION.

These officials may not further re-delegate this authority

3. EFFECTIVE DATE.

The delegations become effective upon date of signature.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on September 2, 2015.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	06/23/1010	N/a	OC/OO/ OM/OMP	Commissioner of Food and Drugs
Revision	06/04/2010	N/a	OC/OA/ OM/OMP	Margaret A. Hamburg M.D., Commissioner of Food and Drugs
Revision	09/02/2015	N/a	CDER/OM	Commissioner of Food and Drugs