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: 21 December 2021

1. Authority Delegated and To Whom Delegated.

A. The officials listed below 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) Center for Drug Evaluation and Research (CDER) Director and Deputy Directors.

(2) CDER/Office of Generic Drugs (OGD) Director.

(3) CDER/Office of New Drugs (OND) Director.

(4) CDER/OND/Office of Rare Diseases, Pediatrics, Urology, and Reproductive Medicine (ORDPURM) Director.

(5) CDER/Office of Pharmaceutical Quality (OPQ) Director.

B. The officials listed below 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 their respective organization:

(1) CDER Director and Deputy Directors.

(2) CDER/OGD Director.

(3) CDER/OND Director.

(4) CDER/OND/ORDPURM Director.

(5) CDER/OPQ Director.

(6) Center for Devices and Radiological Health (CDRH) Director, Deputy Center Director for Science, and Deputy Center Director for Policy.

(7) CDRH/Office of Product Evaluation and Quality (OPEQ) Director.

(8) Center for Food Safety and Applied Nutrition (CFSAN) Director and Deputy Directors.

(9) CFSAN/Office of Cosmetics and Colors (OCAC) Director, Deputy Director, and Associate Director

C. The officials listed below 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) CDER Director and Deputy Directors.

(2) CDER/OGD Director.

(3) CDER/OND Director.

(4) CDER/OND/ORDPURM Director.

(5) CDER/OPQ Director.

D. The officials listed below are authorized to issue 180-day tentative responses to citizen petitions on food and cosmetic matters under 21 CFR 10.30(e)(2)(iv) that relate to the assigned functions of their respective organization:

(1) CFSAN Director and Deputy Directors.

(2) CFSAN/Office of Compliance (OC) Director and Deputy Director.

(3) CFSAN/OCAC Director, Deputy Director, and Associate Director.

(4) CFSAN/Office of Dietary Supplement Programs (ODSP) Director and Deputy Director.

(5) CFSAN/Office of Food Additive Safety (OFAS) Director and Deputy Director.

(6) CFSAN/Office of Food Safety (OFS) Director and Deputy Directors.

(7) CFSAN/Office of Nutrition and Food Labeling (ONFL) Director and Deputy Director.

E. The officials listed below are authorized to issue 180-day tentative responses to citizen petitions on animal food and drug matters under 21 CFR 10.30(e)(2)(iv) that relate to the assigned functions of their respective organization:

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

F. The officials listed below are authorized to issue 180-day tentative responses to citizen petitions on biological product matters under 21 CFR 10.30(e)(2)(iv) that relate to the assigned functions of their respective organization:

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

(2) CDER Director and Deputy Directors.

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

G. The officials listed below are authorized to issue 180-day tentative responses to citizen petitions on drug product matters under 21 CFR 10.30(e)(2)(iv) that relate to the assigned functions of their respective organization:

(1) CBER Director and Deputy Director.

(2) CDER Director and Deputy Directors.

(3) CDER/ORP Director and Deputy Director.

H. The officials listed below are authorized to issue 180-day tentative responses to citizen petitions on medical device matters under 21 CFR 10.30(e)(2)(iv) that relate to the assigned functions of their respective organization:

(1) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.

I. The officials listed below are authorized to issue 180-day tentative responses to citizen petitions on tobacco product matters under 21 CFR 10.30(e)(2)(iv) that relate to the assigned functions of their respective organization:

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

(2) CTP/Office of Regulations (OR) Director.

J. The officials listed below 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 Staff Manual Guides (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) CBER Director and Deputy Director.

(2) CDER Director and Deputy Directors.

(3) CDER/OGD Director.

(4) CDER/OND Director.

(5) CDER/OPQ Director.

K. The officials listed below 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) CDER Director and Deputy Directors.

(2) CDER/OGD Director.

(3) CDER/OND Director.

(4) CDER/OPQ Director.

L. The officials listed below are authorized to issue responses to citizen petitions submitted under 21 CFR 10.30 seeking a determination of the suitability of an abbreviated new drug application for a drug product except for those drug products listed in 21 CFR 314.440(b):

(1) CDER/OGD Director and Deputy Director.

M. The officials listed below are authorized to issue responses to citizen petitions submitted under 21 CFR 10.30 seeking a determination of the suitability of an abbreviated new drug application for those drug products listed in 21 CFR 314.440(b):

(1) CBER/Office of Blood, Research and Review (OBRR) Director and Deputy Director.

(2) CBER/Office of Tissues and Advanced Therapies (OTAT) Director and Deputy Director.

(3) CBER/Office of Vaccines Research and Review (OVRR) Director and Deputy Director.

N. The officials listed below, for drugs assigned to their organization, 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) CBER Director and Deputy Director.

(2) CDER Director and Deputy Directors.

(3) CDER/OGD Director.

(4) CDER/OND Director.

(5) CDER/OPQ Director.

O. The officials listed below 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 an investigational new animal drug for animal use containing a chlorofluorocarbon in accordance with 21 CFR 2.125(c) and (f)(2):

(1) CVM Director and Deputy Directors.

P. The officials listed below 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) CVM/Office of New Animal Drug Evaluation (ONADE) Director and Deputy Director.

Q. The officials listed below 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 they are authorized to take 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) CVM Director and Deputy Directors.

R. The officials listed below 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 821:

(1) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.

(2) CDRH/OPEQ Director and Deputy Directors.

S. The officials listed below 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 their respective organization:

(1) CFSAN Director and Deputy Directors.

(2) CFSAN/OC Director and Deputy Director.

(3) CFSAN/OCAC Director, Deputy Director, and Associate Director.

(4) CFSAN/ODSP Director and Deputy Director.

(5) CFSAN/OFAS Director and Deputy Director.

(6) CFSAN/OFS Director and Deputy Directors.

(7) CFSAN/ONFL Director and Deputy Director.

T. The officials listed below are authorized to grant or deny petitions submitted under 21 CFR 10.30, and petitions for administrative stays of action submitted under 21 CFR 10.35, on medical device, electronic product radiation control, and mammography that relate to the assigned functions of their respective organization:

(1) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.

U. The officials listed below are authorized to grant or deny petitions submitted under 21 CFR 10.30, and petitions for administrative stays of action submitted under 21 CFR 10.35, that pertain exclusively to tobacco product matters that relate to the assigned functions of their respective organization:

(1) CTP Director and Deputy Director.

(2) CTP/OR Director.

V. The officials listed below are authorized to grant or deny, in whole or in part, citizen petitions submitted under 21 CFR 10.30, and petitions for administrative stays of action submitted under 21 CFR 10.35, that pertain exclusively to animal food and drug matters that relate to the assigned functions of their respective organization:

(1) CVM Director and Deputy Directors.

2. Limitations

These delegations exclude the authority to submit reports to Congress.

3. Redelegation.

These officials may not further redelegate these authorities.

4. Effective Date.

The Acting Commissioner of Food and Drugs approved this delegation, via memorandum, on 21 December 2021.

Status	Date Approved	Location of Change History	Contact	Approving Official
Initial	04/29/2009	N/A	OC/ OA/ OM/OMP	Joshua M. Shafstein, M.D. Acting Commissioner of Food and Drugs
Revision	06/23/2009	N/A	OC/ OA/ OM/OMP	Margaret A. Hamburg, M.D. 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	OMPT/ CDER/ OM	Stephen Ostroff, M.D. Acting Commissioner of Food and Drugs

Status	Date Approved	Location of Change History	Contact	Approving Official
Revision	12/21/2021	N/A	CDER/ OM	Janet Woodcock, M.D. Acting Commissioner of Food and Drugs