SMG 1410.114

FDA STAFF MANUAL GUIDES, VOLUME II – DELEGATIONS OF AUTHORITY

REGULATORY – HUMAN DRUGS AND ANIMAL DRUGS

GRANT OR DENIAL OF REQUESTS FOR CERTIFICATION OF DESIGNATED MEDICAL GASES AND AMENDMENTS TO SUCH REQUESTS; APPROVAL OF SUPPLEMENTS; AND OTHER REGULATORY ACTIONS

Effective Date: December 29, 2017

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

A. The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) with regard to the grant or denial of requests to:

1) add a new gas to the list of gases eligible for certification as a designated medical gas for human use under § 575 and § 576 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360ddd and 360ddd-1), and

2) add an indication for use to the approved uses under § 576(a)(3)(A)(i) of the Act; the grant or denial of amendments to certification requests; the approval of supplemental applications related to gases for which granted certification requests are in effect; and any other regulatory actions related to gases for which granted certification requests are in effect:

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

b. Director and Deputy Directors, Office of New Drugs (OND), CDER, OMPT.

c. Director and Deputy Directors, Office of Pharmaceutical Quality (OPQ), CDER, OMPT.

d. Director, Deputy Director, and Senior Scientific Director, Office of New Drug Products (ONDP), OPQ, CDER, OMPT.

e. Director and Deputy Director, Division of New Drug Products II (DNPII), ONDP, OPQ, CDER, OMPT.

f. Director and Deputy Director, Office of Program and Regulatory Operations (OPRO), OPQ, CDER, OMPT.

g. Associate Director for Regulatory Affairs, OPRO, OPQ, CDER, OMPT.

h. Director and Deputy Directors, Divisions of Regulatory Business Process Management I (DRBPMI), OPRO, OPQ, CDER, OMPT.

i. Director and Deputy Directors, Divisions of Regulatory Business Process Management II (DRBPMII), OPRO, OPQ, CDER, OMPT.

j. Director and Deputy Directors, Office of Surveillance and Epidemiology (OSE), CDER, OMPT.

B. The following officials are authorized to perform all the functions of the Commissioner with regard to the grant or denial of requests for certification of medical gases as designated medical gases for human use that have been submitted under § 576 of the Federal Food, Drug and Cosmetic Act (the Act) (21 U.S.C. 360ddd-1), including amendments to or resubmissions of certification requests; the approval or denial of supplemental applications related to gases for which granted certification requests are in effect; the withdrawal, suspension, or revocation of a certification; and any other regulatory actions related to gases for which granted certification requests are in effect:

1) Director and Deputy Directors, CDER, OMPT.

2) Director and Deputy Director, OND, CDER, OMPT.

3) Director and Deputy Director, OPQ, CDER, OMPT.

4) Director and Deputy Directors, ONDP, OPQ, CDER, OMPT.

5) Director and Deputy Directors, OPRO, OPQ, CDER, OMPT.

6) Associate Director for Business Operations, OPRO, OPQ, CDER, OMPT.

7) Associate Director for Regulatory Affairs, OPRO, OPQ, CDER, OMPT.

8) Director and Deputy Director, OSE, CDER, OMPT.

C. The following officials are authorized to perform all the functions of the Commissioner with regard to the grant or denial of requests to:

1) add a new gas to the list of gases eligible for certification as a designated medical gas for animal use under § 575 and § 576 of the Federal Food, Drug and Cosmetic Act (the Act) (21 U.S.C. 360ddd and 360ddd-1), and

2) add an additional indication for use to the approved uses under § 576(a)(3)(A)(i) of the Act (21 U.S.C. 360ddd-1(a)(3)(A)(i)).

a. Director and Deputy Director, Center for Veterinary Medicine (CVM), Office of Food and Veterinary Medicine (OFVM).

b. Director and Deputy Director, Office of New Animal Drug Evaluation (ONADE), CVM, OFVM.

D. The following officials are authorized to perform all the functions of the Commissioner with regard to the grant or denial of requests for certification of medical gases as designated medical gases for animal use that have been submitted under § 576 of the Act (21 U.S.C. 360ddd-1), including the grant or denial of amendments to or resubmissions of certification requests; the approval or denial of supplemental applications related to gases for which granted certification requests are in effect; the withdrawal, suspension, or revocation of a certification; and any other regulatory actions related to gases for which granted certification requests are in effect:

1) Director and Deputy Director, CVM, OFVM.

2) Director and Deputy Director, ONADE, CVM, OFVM.

3) Director, Division of Business Information and Science Management (DBISM), ONADE, CVM, OFVM.

2. REDELEGATION.

These officials may not further redelegate these authorities.

3. EFFECTIVE DATE.

The delegations become effective upon date of signature.

The Commissioner of Food and Drugs approved this delegation on December 29, 2017.

STATUS	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL

STATUS	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	01/08/2015	N/a	CDER/OM	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs
Revision	12/29/2017	N/a	OMPT/ CDER/OM	Scott Gottlieb, M.D., Commissioner of Food and Drugs

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