DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

FEB 18 2009

Mr. Thomas K. Thompson, Senior Health Physicist
U.S. Nuclear Regulatory Commission, Region I
Division of Nuclear Materials Safety
Commercial and R&D Branch
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

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Re: NRC License No. 19-30771-01
Docket No. 03036120
Control No. 141772

STATEMENT OF INTENT

As Deputy Commissioner for Operations & Chief Operating Officer of the U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS), I exercise expressed authority and responsibility to request from the FDA funds for decommissioning activities associated with operations authorized by U.S. Nuclear Regulatory Commission (NRC) Material License No 19-30771-01. This authority is established by FDA Staff Manual Guide 1410.21, General Redelegations of Authority from the Commissioner to other Officers of the Food and Drug Administration paragraph 1(b)(1). Within this authority, I intend to request that funds be made available, when necessary, in the amount of $3,205,000 to decommission the Harvey W. Wiley Building (CPK 1), 5100 Paint Branch Parkway, College Park, Maryland 20740; Muirkirk Road Complex Facilities, Laurel, Maryland 20708 and any Temporary Job Sites anywhere in the United States where the U.S. NRC maintains jurisdiction for regulating the use of licensed material, including areas of exclusive Federal jurisdiction within Agreement States. I intend to request and obtain these funds sufficiently in advance of the decommissioning to prevent delay of required activities.

A copy of the FDA Staff Manual Guide 1410.21, effective May 15,2007 is enclosed as evidence that I am authorized to represent the Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, Department of Health and Human Services, in this transaction.

John R. Dyer
Deputy Commissioner for Operations
and Chief Operating Officer

Enclosures

NONNEGOTIABLE

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FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - GENERAL REDELEGATIONS OF AUTHORITY

SMG 1410.21 - GENERAL REDELEGATIONS OF AUTHORITY FROM THE COMMISSIONER TO OTHER OFFICERS OF THE FOOD AND DRUG ADMINISTRATION

1. AUTHORITY DELEGATED, TO WHOM DELEGATED, AND REDELEGATION.

A. Final authority of the Commissioner of Food and Drugs (Commissioner) is redelegated as set forth in these 1410 series of the Agency's Staff Manual Guides (SMGs). The Commissioner may continue to exercise all authority delegated in these SMGs.

B. The following officials are authorized to perform all of the functions of the Commissioner. These officials may not further redelegate this authority, or any part of this authority, except as elsewhere specified:

I . Deputy Commissioner;

2. Deputy Commissioner for Policy;

3. Deputy Commissioner for Operations;

4. Deputy Commissioner for International and Special Programs;

5. Associate Commissioner for Regulatory Affairs;

6. Chief Counsel, Office of the Chief Counsel;

7. Associate Commissioner for External Relations;

8. Associate Commissioner for Management;

9. Associate Commissioner for Policy and Planning;

10. Associate Commissioner for Legislation; and

11. Associate Commissioner for International Activities and Strategic Initiatives.

C.1. The Federal Vacancies Reform Act of 1998 (Vacancies Reform Act) applies if the Commissioner dies, resigns, or is otherwise unable to perform the functions and duties of the Office of the Commissioner. During an absence of the Commissioner that does not trigger the requirements of the Vacancies Reform Act, the first official in the following order who is available or the official in the following list who has been

designated by the Commissioner to act shall act as Commissioner:

a. Deputy Commissioner;

b. Deputy Commissioner for Policy;

c. Deputy Commissioner for Operations;

d. Deputy Commissioner for International and Special Programs; or

e. Associate Commissioner for Regulatory Affairs

These officials may not further redelegate this authority.

2. When the Vacancies Reform Act applies, the Deputy Commissioner shall act as Commissioner unless the Deputy Commissioner does not meet the requirements of the Vacancies Reform Act or the President has directed someone else to act as Commissioner pursuant to the Vacancies Reform Act.

D. Authority delegated to a position by title may be exercised by a person officially designated to serve in that position in an acting capacity or on a temporary basis, unless prohibited by a restriction in the document designating him/her as "acting" or unless not legally permissible.

E.1. The Associate Commissioner for External Relations is authorized to make determinations that advisory committee meetings are concerned with matters listed in 5 U.S.C. 552(b) and therefore may be closed to the public in accordance with Staff Manual Guide 1410.10, paragraph 1.A.17.

2. The Associate Commissioner for External Relations is authorized to perform other associated advisory committee functions (e.g., establishing technical and scientific review groups (advisory committees)); appointing and paying members; approving waivers to appoint members to established advisory committees; renewing and rechartering of established advisory committees; amending charters of established advisory committees; and terminating established advisory committees.

3. The Associate Commissioner for External Relations is authorized to approve conflict of interest waivers for special Government employees serving on advisory committees in accordance with 18 U.S.C. 208(b)(3), as amended.

4. The Associate Commissioner for External Relations is authorized to select temporary members to advisory committees if such voting members are serving on an advisory committee managed by another center.

5. The Associate Commissioner for External Relations is authorized to grant waivers under 21 U.S.C. 355 (n)(4): wherein the [panel] member or the member's immediate family could gain financially from the advice given. A waiver may be granted of any conflict of interest requirement upon public disclosure of such conflict of interest if such waiver is necessary to afford the panel essential expertise, except a waiver may not be granted when the member's own scientific work is involved.

6. The Associate Commissioner for External Relations is authorized to issue Federal Register notices relating to advisory committee activities.

7. The Associate Commissioner for External Relations may not further redelegate

these authorities. In addition, in the event of absence or a vacancy in the position, the Associate Commissioner for Policy and Planning is designated to perform these functions.

F.1. The Associate Commissioner for Policy and Planning (ACPP) and the Assistant Commissioner for Policy (ACP) are authorized to perform any of the functions of the Commissioner with respect to the issuance of Federal Register notices and proposed and final regulations of the Food and Drug Administration. These officials may not further redelegate this authority.

2. The ACPP and the ACP are authorized to issue responses to the following matters under part 10 of Title 21, Code of Federal Regulations (21 CFR) as follows and these officials may not further redelegate this authority:

a. Requests for waiver, suspension, or modification of procedural requirements under section 10.19 of 21 CFR;

b. Citizen petitions under section 10.30 of 21 CFR;

c. Petitions for reconsideration under section 10.33 of 21 CFR;

d. Petitions for stay under section 10.35 of 21 CFR; or

e. Requests for advisory opinions under section 10.85 of 21 CFR.

3. With respect to any matter delegated to the ACPP and the ACP under this paragraph, the ACPP and the ACP are authorized to perform the function of the Commissioner under sections 10.40, 10.45, 10.50, 10.55, 10.60, 10.65, 10.80, 10.90, and 10.95 of 21 CFR and of the Deputy Commissioner under section 10.206(g) and (h) of 21 CFR. These officials may not further redelegate this authority.

4. The ACPP and the ACP are authorized under the Regulatory Flexibility Act (5 U.S.C. 605(b)) to certify that a proposed or final rule, if issued, will not have a significant economic impact on a substantial number of small entities. The ACPP and the ACP may further redelegate this authority

5. The ACP is authorized to make all determinations and findings under 21 CFR Part 15, and to waive, suspend, or modify any procedural requirements related to Part 15 under section 10.19 of 21 CFR.

G. The following officials are authorized to perform all the functions of the officials under them in their respective offices and they may not further redelegate this authority:

1. Associate Commissioner for External Relations;

2. Associate Commissioner for Management;

3. Associate Commissioner for Policy and Planning;

4. Associate Commissioner for Legislation; and

5. Associate Commissioner for International Activities and Strategic Initiatives.

H.1. The Chief Mediator and Ombudsman and the Deputy Chief Mediator and

Ombudsman, Office of External Relations, are authorized to act upon requests for reconsideration of any user fee decisions under section 735 of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 379h) made by such officers and the former Deputy User Fee Waiver Officer prior to July 1, 1999. These officials may not further redelegate this authority. (See SMG 1410.109 for the user fee-related redelegation to officials within the Center for Drug Evaluation and Research.)

2. The Associate Commissioner for Management (ACM), Office of Management (OM), is authorized to perform the functions of the Commissioner under:

a. section 736(d)(1)(c) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 379h(d)(1)(C)), as amended, to waive or reduce prescription drug user fees in situations where he or she finds that "the fees will exceed the anticipated present and future costs." The ACM may further redelegate the authority in this paragraph in whole or in part to the Director, Office of Financial Management (OFM), Office of Management (OM).

b. section 740(d)(1)(B) of the FFDCA, to waive or reduce animal drug user fees, for waiver or reduction request made on the basis that the fees assessed exceed the costs to FDA for reviewing applications. The ACM may further redelegate the authority in this paragraph in whole or in part to the Director, OFM, OM.

c. section 736(c)(4) of the FFDCA, as amended by the Prescription Drug User Fee Act Amendments of 2002, to establish application, product, and establishment fees under section 736(a), based on the revenue amounts established under section 736(b) and the adjustments under 736(c). The ACM may further redelegate the authority in this paragraph in whole or in part.

d. section 738 of the FFDCA, as added by the Medical Device User Fee Modernization Act of 2002 (MDUFMA), to adjust and set fee rates for medical device applications each year and to adjust, when necessary, the Small Business threshold. The ACM may further redelegate the authority in this paragraph in whole or in part.

e. section 740(c)(4) of the FFDCA, to adjust and set animal drug user fee rates; and to refund animal drug user fees. The ACM may further redelegate the authority in this paragraph in whole or in part.

3. The Deputy Commissioner for International and Special Programs is designated as the User Fee Appeals Officer. The User Fee Appeals Officer is authorized to hear and decide user fee waiver appeals. The decision of the User Fee Appeals Officer will constitute final agency action on such matters. The User Fee Appeals Officer may not further redelegate this authority.

4. The Associate Commissioner for International Activities and Strategic Initiatives is authorized under section 503(g)(4)(E)(ii) of the Federal, Food, Drug and Cosmetic Act, as added by section 204 of the MDUFMA), with respect to combination products the following: "During the review process, any dispute regarding the substance of premarket review may be presented to the Commissioner of Food and Drug after first being considered by the agency center with primary jurisdiction of the premarket review, under the scientific dispute resolution procedures for such center. The Commissioner of Food and Drugs shall consult with the Director of the Office [of Combination Products, Office of the Commissioner] in resolving the substantive disputes."

I. The Associate Commissioner for Management is authorized to perform all of the

administrative authorities (i.e., financial, personnel, facilities management, property management, etc.) of the Commissioner. These authorities may be further redelegated, except when specifically prohibited.

J. The following officials are authorized under section 564(c) of the Federal Food, Drug, and Cosmetic Act, requiring "consultation with the Director of the National Institutes of Health and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the circumstances of the emergency involved)" prior to issuing an emergency use authorization (EUA):

1. Assistant Commissioner for Counterterrorism Policy;

2. Director, Center for Biologics Evaluation and Research;

3. Director, Center for Drug Evaluation and Research; or

4. Director, Center for Devices and Radiological Health.

K. Unless specifically noted, the persons to whom the Commissioner has delegated authority in the 1410 series SMGs may not further redelegate that authority.

2. EFFECTIVE DATE.

The Commissioner of Food and Drugs apprbved this delegation, via memorandum, on May 15,2007.

Staff Manual Guides Table of Contents

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