DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
Winchester Engineering and Analytical Center

109 Holton Street
Winchester, Massachusetts 01890
(781) 729-5700
FAX: (781) 729-3593

February 6, 2006

Licensing Assistant Section
Nuclear Materials Safety Branch
U. S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406-1415

License: 20-08361-01
Exp. Date: February 26, 2006
Docket No. 030-04675
Control No. 138288
Program Code 03610

Gentlemen/Madams:

We had previously sent you our renewal of subject NRC License. Our Statement of Intent for the Decommissioning of this Facility that was included was written by the previous Associate Commissioner for Management and Chief Financial Officer. Attached is the new Letter with the revised financial costs for the Decommissioning of this Facility. Also attached are supporting documents for this delegation of Authority.

If there are any questions regarding this Statement of Intent, please contact Edmond J. Baratta, Radiation Safety Officer at (781)729-5700, extension781

Sincerely yours,
Martin J. Finkelson
Martin J. Finkelson
Director, WEAC

Attachments: Statement of Intent
Delegation of Authority

cc: Edmond J. Baratta
Radiation Safety Officer/WEAC/ORA

138288

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

JAN 31 2006

U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

NRC License No. 20-08361-01
Docket No. 03004675
Control No. 134498

STATEMENT OF INTENT

As Associate Commissioner for Management of the U.S. Food and Drug Administration (FDA), Department of Health and Human Services, I exercise expressed authority and responsibility to request FDA funds for decommissioning activities associated with the operations authorized by the Nuclear Regulatory Commission Material License No. 20-08361-01. This authority is established by paragraph 1(i) of FDA Staff Manual Guide 1410.21, *General Redelegations of Authority from the Commissioner to Other Officers of the Food and Drug Administration.* The FDA has estimated the cost of decommissioning its facilities under the aforementioned license to be $1,197,000. Within my authority noted above, I intend to request that funds be made available, when necessary, in the estimated amount of $1,300,000 to decommission facilities authorized under the

Department of Health and Human Services
U.S. Food and Drug Administration
Winchester Engineering and Analytical Center
109 Holton Street
Winchester, MA 01890.

I intend to request and obtain these funds sufficiently in advance of the decommissioning to prevent delay of required activities.

A copy of FDA Staff Manual Guide 1410.21, effective February 7, 2005 is enclosed as evidence that I am authorized to represent the Department of Health and Human Services, U.S. Food and Drug Administration, Winchester Engineering and Analytical Center, in this transaction.

Kathleen D. Heuer
Associate Commissioner for Management
and Chief Financial Officer

Enclosure

NONNEGOTIABLE

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:

(1) 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:

(i) Deputy Commissioner;

(ii) Deputy Commissioner for Policy;

(iii) Deputy Commissioner for Operations;

(iv) Deputy Commissioner for International and Special Programs; or

(v) 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:

(i) Requests for waiver, suspension, or modification of procedural requirements under section 10.19 of 21 CFR;

(ii) Citizen petitions under section 10.30 of 21 CFR;

(iii) Petitions for reconsideration under section 10.33 of 21 CFR;

(iv) Petitions for stay under section 10.35 of 21 CFR; or

(v) 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.

(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:

(i) 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).

(ii) 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.

(iii) 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.

(iv) 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.

(v) 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 authorit

(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) 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**. On February 7, 2005, this delegation was approved and became effective via memorandum, signed by Lester M. Crawford, D.V.M., Ph.D., Acting Commissioner of Food and Drugs.

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