FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OFFICE OF REGULATORY SCIENCE

Br. 3

REC RG 1 03/01 '19 PM 02 45

February 28, 2019

Licensing Assistance Team
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
2100 Renaissance Boulevard
Suite 100
King of Prussia, PA 19406-2713

SUBJECT: License No. 20-08361-01; Request for License Amendment for the U.S. Food and Drug Administration Winchester Engineering and Analytical Center; Addition of Location

Dear Licensing Assistance Team:

03004675

We request the following amendment be made to our NRC License No. 20-08361-01:

1. We request to use licensed material listed in subitem No 6.AA. at the following new address:

Pacific Northwest Laboratory
22201 23rd Drive SE
Bothell, WA 98021-4421

We consider the classification of the laboratory as Type C, defined in Appendix K of NUREG-1556, Volume 11, "Program-Specific Guidance About Licenses of Broad Scope". The Pacific Northwest Laboratory located in Bothell, Washington is a conventional modern laboratory with adequate ventilation and non-porous work surfaces. The maximum activity of tritium processed at one time during laboratory operations is less than 1 mCi.

Attached is an updated Statement of Intent which includes the Pacific Northwest Laboratory location as well as the location in Jamaica, New York. We will include these locations in our next Decommissioning Funding Plan which is due May 9, 2020.

Please contact Elon Malkin if you have questions or need additional information.
He can be reached by phone at (781) 756-9814 or by email at Elon.Malkin@fda.hhs.gov.

Sincerely,

Brian L. Baker -S
Digitally signed by Brian L. Baker -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Brian L. Baker -S, 0.9.2342.19200300.100.1.1=2000359907
Date: 2019.02.28 11:19:23 -05'00'

Brian L. Baker, P.E.
Director

U.S. Food and Drug Administration
Winchester Engineering & Analytical Center
109 Holton Street
Winchester, MD 01890
www.fda.gov

611525

NMSS/RGN1 MATERIALS-002

NRC FORM 313 (10-2017) 10 CFR 30, 32, 33, 34, 35, 36, 37, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120 **EXPIRES: 06/30/2019**

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Information Services Branch (T-2 F43), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE CURRENT VOLUMES OF THE NUREG-1556 TECHNICAL REPORT SERIES ("CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES") FOR DETAILED INSTRUCTIONS FOR COMPLETING THIS FORM: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/. SEND TWO COPIES OF THE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

MATERIALS SAFETY LICENSING BRANCH
DIVISION OF MATERIAL SAFETY, STATE, TRIBAL AND RULEMAKING PROGRAMS
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,

SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

IF YOU ARE LOCATED IN:

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING,

SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- ☐ A. NEW LICENSE
- ☑ B. AMENDMENT TO LICENSE NUMBER 20-08361-01
- ☐ C. RENEWAL OF LICENSE NUMBER

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include zip code)*

Winchester Engineering and Analytical Center (WEAC)
Department of Health and Human Services
Food and Drug Administration
109 Holton Street Winchester Massachusetts 01890-1197

3. ADDRESS WHERE LICENSED MATERIALS WILL BE USED OR POSSESSED

FDA ORA WEAC, 109 Holton Street, Winchester, Massachusetts; FDA ORA Northeast Lab, 158-15 Liberty Avenue, Jamaica, New York; FDA CDER, 645 South Newstead Avenue, Saint Louis,

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Elon Malkin, Radiation Safety Officer

BUSINESS TELEPHONE NUMBER	BUSINESS CELLULAR TELEPHONE NUMBER
781-756-9814	240-460-3141

BUSINESS E-MAIL ADDRESS
Elon.Malkin@fda.hhs.gov

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
   a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (Fees required only for new applications, with few exceptions*) *(See 10 CFR 170 and Section 170.31)*
***Amendments/Renewals that increase the scope of the existing license to a new or higher fee category will require a fee.**

FEE CATEGORY [ ] AMOUNT ENCLOSED $ [ ]

PER THE DEBT COLLECTION IMPROVEMENT ACT OF 1996 (PUBLIC LAW 104-134), YOU ARE REQUIRED TO PROVIDE YOUR TAXPAYER IDENTIFICATION NUMBER. PROVIDE THIS INFORMATION BY COMPLETING NRC FORM 531: https://www.nrc.gov/reading-rm/doc-collections/forms/nrc531info.html.

13. CERTIFICATION. *(Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.*

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.
WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Brian Baker, WEAC Lab Director	Brian L. Baker -S Digitally signed by Brian L. Baker -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Brian L. Baker -S, 0.9.2342.19200300.100.1.1=2000359907 Date: 2019.02.28 11:22:12 -05'00'	

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED $	CHECK NUMBER	COMMENTS
APPROVED BY				DATE	

Date: November 11, 2018

TO: U.S. Nuclear Regulatory Commission
Region I
2100 Renaissance Blvd.
King of Prussia, PA 19406-2713

STATEMENT OF INTENT

As Deputy Commissioner for Operations/COO of the U.S. Food and Drug Administration (FDA), I exercise express authority and responsibility to request from 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 FDA Staff Manual Guide 1410.21. Within this authority, I intend to request that funds be made available when necessary in the amount of $1,907,433 to decommission The Department of Health and Human Services, Food and Drug Administration, Winchester Engineering and Analytical Center, 109 Holton Street, Winchester, MA, 01890; The Department of Health and Human Services, Food and Drug Administration, Northeast Laboratory, 158-15 Liberty Avenue, Jamaica, NY 11433; and The Department of Health and Human Services, Food and Drug Administration, Pacific Northwest Laboratory, 22201 23rd Drive SE, Bothell, WA 98021-4421.

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

A copy of FDA Staff Manual Guide 1410.21 is attached as evidence that I am authorized to represent The Department of Health and Human Services, Food and Drug Administration, Winchester Engineering and Analytical Center.

James M. Sigg
Deputy Commissioner for Operations/COO
Food and Drug Administration
Date:

Attachment:
FDA Staff Manual Guide 1410.21

NONNEGOTIABLE

SMG 1410.21

FDA STAFF MANUAL GUIDES, VOLUME II – DELEGATIONS OF AUTHORITY

REGULATORY – GENERAL REDELEGATIONS OF AUTHORITY

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

Effective Date: September 21, 2016

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

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

B. The following officials are authorized to perform all delegable 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 for Medical Products and Tobacco, Office of Medical Products and Tobacco (OMPT).

2. Chief of Staff, Office of the Commissioner (OC).

3. Deputy Commissioner for Operations and Chief Operating Officer, Office of Operations (OO).

4. Deputy Commissioner for Policy, Planning, Legislation and Analysis, Office of Policy, Planning, Legislation and Analysis (OPPLA).

5. Deputy Commissioner for Foods and Veterinary Medicine, Office of Foods and Veterinary Medicine (OFVM).

6. Deputy Commissioner for Global Regulatory Operations and Policy, Office of Global Regulatory Operations and Policy (OGROP).

7. Chief Scientist, Office of the Chief Scientist (OCS), OC.

8. Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs (ORA), OGROP.

C. 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.

1. 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 lead the Agency (specific delegations provided below do not limit the general delegations provided by this section to the designated officials who are authorized to perform all of the delegable functions of the Commissioner):

    a. Deputy Commissioner for Foods and Veterinary Medicine, OFVM.

    b. Deputy Commissioner for Medical Products and Tobacco, (OMPT).

    c. Chief of Staff, OC.

    d. Deputy Commissioner for Operations and Chief Operating Officer, OO.

    e. Deputy Commissioner for Policy, Planning, Legislation and Analysis, OPPLA.

    f. Deputy Commissioner for Global Regulatory Operations and Policy, OGROP.

    g. Chief Scientist, OCS, OC.

    h. Associate Commissioner for Regulatory Affairs, ORA, OGROP.

    i. Director, Center for Drug Evaluation and Research (CDER), OMPT.

2. When the Vacancies Reform Act applies, the Deputy Commissioner for Foods and Veterinary Medicine, OFVM, shall act as Commissioner unless the Deputy Commissioner for Foods and Veterinary Medicine, OFVM, 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 them as "acting" or unless not legally permissible.

E. 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. Deputy Commissioner for Medical Products and Tobacco, OMPT.

2. Deputy Commissioner for Operations and Chief Operating Officer, OO.

3. Chief Scientist, OCS, OC.

4. Deputy Commissioner for Foods and Veterinary Medicine, OFVM.

5. Deputy Commissioner for Global Regulatory Operations and Policy, OGROP.

6. Associate Commissioner for Regulatory Affairs, ORA, OGROP.

7. Chief Counsel, Office of the Chief Counsel.

8. Deputy Commissioner for Policy, Planning, Legislation and Analysis, OPPLA.

F. The Deputy Commissioner for Medical Products and Tobacco, OMPT is authorized:

1. 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 Title 21, Code of Federal Regulations (21 CFR) 14.27.

2. 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. To approve conflict of interest waivers for Special Government Employees (SGEs) and regular government employees serving on advisory committees in accordance with 21 U.S.C. 379d-1 and 18 U.S.C. 208(b)1 and 208(b)(3), as amended.

4. To select temporary members to advisory committees if such voting members are serving on an advisory committee managed by another Center.

5. To issue Federal Register (FR) Notices relating to advisory committee activities.

6. To further redelegate the authorities in paragraphs F.1-F.5 above to the Associate Commissioner for Special Medical Programs, Office of Special Medical Programs (OSMP), OMPT. In addition, in the event of absence or a vacancy in the position, the Deputy Commissioner for Policy, Planning, Legislation and Analysis, OPPLA, is designated to perform the functions in paragraphs F.1.-F.5 above.

7. Under Section 503(g)(4)(E)(ii) of the Federal, Food, Drug and Cosmetic Act (FFDCA), as added by Section 204 of the Medical Device User Fee Modernization Act of 2002 (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 Drugs 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, OSMP, OMPT in resolving the substantive dispute."

G. The Deputy Commissioner for Policy, Planning, Legislation and Analysis, OPPLA, the Associate Commissioner for Policy, Office of Policy (OP), OPPLA, and the Associate Commissioner for Public Health Strategy and Analysis, Office of Public Health Strategy and Analysis (OPHSA), OPPLA, are authorized:

1. To perform any of the functions of the Commissioner with respect to the issuance of FR notices and proposed and final regulations of the Food and Drug Administration. This authority may not be further redelegated.

2. To issue responses to the following matters under part 10 of 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.

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

3. With respect to any matter delegated to the Deputy Commissioner for Policy, Planning, Legislation and Analysis, OPPLA, the Associate Commissioner for Policy, OP, OPPLA, and the Associate Commissioner for Public Health Strategy and Analysis, OPHSA, OPPLA, under this paragraph, the Deputy Commissioner for Policy, Planning, Legislation and Analysis, OPPLA, the Associate Commissioner for Policy , OP, OPPLA, and the Associate Commissioner for Public Health Strategy and Analysis, OPHSA,OPPLA, are authorized to perform the functions of the Commissioner under Section 10.40, 10.45, 10.50, 10.55, 10.60, 10.65, 10.80, 10.90, and 10.95 of 21 CFR and of a Deputy Commissioner under Section 10.206(g) and (h) of 21 CFR. These authorities may not be further redelegated.

4. 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 Deputy Commissioner for Policy, Planning, Legislation and Analysis, OPPLA, the Associate Commissioner for Policy, OP, OPPLA, and the Associate Commissioner for Public Health Strategy and Analysis, OPHSA, OPPLA, may further redelegate this authority.

5. 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.

H. The Associate Director for Policy, Office of Regulatory Policy, CDER, OMPT, is authorized:

1. To waive or reduce prescription drug user fees in situations where he or she finds that such a waiver or reduction: (1) is necessary to protect the public health under Section 736(d)(1)(A) of the FFDCA (21 U.S.C. 379h(d)(1)(A)), as amended; (2) is necessary because the fee would present a significant barrier to innovation under Section 736(d)(1)(B) of the FFDCA (21 U.S.C. 379h(d)(1)(a)), as amended; or (3) is appropriate under Section 736(d)(1)(D) of the FFDCA (21 U.S.C. 379h(d)(1)(D)), as amended because the applicant involved is a small business submitting its first human drug application. These authorities may not be further redelegated.

2. To act upon requests for consideration of any user fee decisions under Section 735 of the FFDCA (21 U.S.C. 379h), other than decisions on fee-exceed-the cost waiver requests, made by such officers and the

former Deputy User Fee Waiver Officer prior to July 1, 1999. These authorities may not be further redelegated.

I. The Director, Policy and Regulations Staff, Office of the Center Director, Center for Veterinary Medicine (CVM), OFVM is authorized:

1. To waive or reduce animal drug user fees in situations where he or she finds that such a waiver or reduction: (1) is necessary because the fee would present a significant barrier to innovation under Section 740(d)(1)(A) of the FFDCA (21 U.S.C. 379j-12(d)(1)(A)), as amended; (2) is necessary because the drug application or supplemental application is intended solely for use of the animal drug in medicated feeds under Section 740(d)(1)(C) of the FFDCA (21 U.S.C. 379j-12(d)(1)(C)), as amended; (3) is necessary because the animal drug application or supplemental animal drug application is intended solely to provide for minor use or minor species indications under Section 740(d)(1)(D) of the FFDCA (21 U.S.C. 379j-12(d)(1)(D)), as amended; or (4) is appropriate under Section 740(d)(1)(E) of the FFDCA (21 U.S.C. 379h(d)(1)(E)), as amended because the applicant involved is a small business submitting its first animal drug application. This authority may not be redelegated.

2. To waive or reduce generic animal drug user fees in situations where he or she finds that such a waiver or reduction is necessary because the animal drug application or supplemental animal drug application is intended solely to provide for minor use or minor species indications under Section 741(d) of the FFDCA (21 U.S.C. 379j-21(d)), as amended.

3. Under any of the above cited provisions of Section 740 and 741 of the FFDCA, to act upon requests for reconsideration of decisions made. This authority may not be redelegated.

J. The Associate Director for Policy and Communications, Office of the Director, CVM, OFVM, is authorized to act upon requests for reconsideration of decisions made under any provision of Sections 740 and 741 of the FFDCA, except for those decisions that pertain to fee-exceed-the cost waiver requests. This authority may not be further redelegated.

K. The Deputy Commissioner for Operations and Chief Operating Officer, OO, is authorized to perform the functions of the Commissioner under:

1. Section 736(d)(1)(c) of the 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 Deputy Commissioner for Operations and Chief Operating Officer, OO, may further redelegate the authority in this paragraph in whole or in part to the Associate Commissioner for Finance, Budget and Acquisitions, Office of Finance, Budget and Acquisitions (OFBA), OO.

2. Section 740(d)(1)(B) of the FFDCA, to waive or reduce animal drug user fees, for waiver or reduction requests made on the basis that the fees assessed exceed the costs to FDA for reviewing applications. The Deputy Commissioner for Operations and Chief Operating Officer, OO, may further redelegate the authority in this paragraph in whole or in part to the Associate Commissioner for Finance, Budge and Acquisitions, OFBA, OO.

3. 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 Deputy Commissioner for Operations and Chief Operating Officer, OO, may further redelegate the authority in this paragraph in whole or in part to the Associate Commissioner for Finance, Budget and Acquisitions, OFBA, OO.

4. Section 738 of the FFDCA, as added by the MDUFMA, to adjust and set fee rates for medical device applications each year. The Deputy Commissioner for Operations and Chief Operating Officer, OO, may further redelegate the authority in this paragraph in whole or in part to the Associate Commissioner for Finance, Budget and Acquisitions, OFBA, OO.

5. Section 740(c)(4) of the FFDCA, to adjust and set new and supplemental animal drug application fees, animal drug sponsor fees, animal drug product fees, and animal drug establishment fees. The Deputy Commissioner for Operations and Chief Operating Officer, OO, may further redelegate the authority in this paragraph in whole or in part to the Associate Commissioner for Finance, Budget and Acquisitions, OFBA, OO.

6. Section 741(c)(3) of the FFDCA, to adjust and set abbreviated application fees, generic new animal drug sponsor fees, and generic new animal drug product fees. The Deputy Commissioner for Operations and Chief Operating Officer, OO, may further redelegate the authority in this paragraph in whole or in part to the Associate Commissioner for Finance, Budget and Acquisitions, OFBA, OO.

7. Section 919(b)(6)) of the FFDCA (21 U.S.C. 387s(c)(6)), to notify each manufacturer and importer of tobacco products subject to this Section of the amount of the quarterly assessment due for such products. The Deputy Commissioner for Operations and Chief Operating Officer, OO, may further redelegate the authority in this paragraph in whole or in part to the Associate Commissioner for Finance, Budget and Acquisitions, OFBA, OO.

8. Under any fees-exceed-cost user fee waiver or reduction sections of the FFDCA noted above, act upon requests for reconsideration of decisions made by such officers. This authority may not be redelegated.

L. The Chief Scientist, OCS, OC, 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.

M. The Deputy Commissioner for Operations and Chief Operating Officer, OO, 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.

N. The following officials are authorized to deny a request to issue an emergency use authorization (EUA) under Section 564 of the FFDCA, and to consult under Section 564(c) of the FFDCA, 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 EUA:

1. Chief Scientist, OCS, OC.

2. Deputy Commissioner for Medical Products and Tobacco, OMPT.

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

4. Director, Center for Drug Evaluation and Research (CDER), OMPT.

5. Director, Center for Devices and Radiological Health (CDRH), OMPT.

O. The following officials are authorized to issue the final decision regarding the disqualification of a clinical investigator, i.e., the investigator's eligibility

to receive investigational articles under 21 CFR 312.70(b), 511.1(c)(2), or 812.119(b):

1. Deputy Commissioner for Medical Products and Tobacco, OMPT.

2. Chief Scientist, OCS, OC.

3. Associate Commissioner for Special Medical Programs, OMPT.

P. The following officials are authorized to sign a consent agreement between the FDA and a clinical investigator regarding the disqualification of the clinical investigator, resulting in the clinical investigator's ineligibility to receive investigational articles under 21 CFR 312.70(b), 511.1(c)(2), or 812.119(b) and containing a binding provision that disqualification pursuant to the consent agreement has the same legal effect as being disqualified pursuant to the relevant regulation after a Part 16 Hearing. These officials may not further redelegate this authority.

1. Director, CBER, OMPT.

2. Director and Deputy Director, Office of Compliance and Biologics Quality (OCBQ), CBER, OMPT.

3. Director, CDER, OMPT.

4. Director and Deputy Director, Office of Compliance (OC), CDER, OMPT.

5. Director and Deputy Director, Division of Scientific Investigations (DSI), OC, CDER, OMPT.

6. Director, CVM, OFVM.

7. Director and Deputy Director, Office of Surveillance and Compliance (OSC), CVM, OFVM.

8. Director, Division of Compliance, OSC, CVM, OFVM.

9. Director, CDRH, OMPT.

10. Deputy Director for Science, CDRH, OMPT.

11. Director, Office of Compliance (OC), CDRH, OMPT.

12. Deputy Director for Medical Affairs, OC, CDRH, OPMT.

2. REDELEGATION.

Except as otherwise provided, 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 these delegations of authority, via memorandum, on September 21, 2016.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	12/07/2009	N/a	OCOA/ OM/OMP	Margaret A. Hamburg, M.D. Commissioner of Food and Drugs
Revision	06/08/2010	N/a	OCOA/ OM/OMP	Margaret A. Hamburg, M.D. Commissioner of Food and Drugs
Revision	10/11/2011	N/a	OO/OM	Margaret A. Hamburg, M.D. Commissioner of Food and Drugs
Revision	07/05/2012	N/a	OO/OBS	Commissioner of Food and Drugs
Revision	09/21/2016	N/a	OO/OHR/ MASS	Robert M. Califf, M.D. Commissioner of Food and Drugs

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NRC FORM 532
(05-2016)

U.S. NUCLEAR REGULATORY COMMISSION

ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Brian L. Baker, Director
US Department of Health and Human Services
Food and Drug Administration
Winchester Engineering and Analytical Center
109 Holton Street
Winchester, Massachusetts 01890-1197

Date
March 7, 2019

License Number(s)
20-08361-01

Mail Control Number(s)
611525

Licensing and/or Technical Reviewer or Branch
Decommissioning, ISFSI and Reactor HP Branch

This is to acknowledge receipt of your: ☑ **Letter and/or** ☑ **Application** **Dated:** February 28, 2019

The initial processing, which included an administrative review, has been performed.

☑ **Amendment** ☐ **Termination** ☐ **New License** ☐ **Renewal**

☑ **There were no administrative omissions identified during our initial review.**

☐ **This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.**

☐ **Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf**

Follow the instructions on the form for submission.

☐ **The following administrative omissions have been identified:**

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region I
U. S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713
(610) 337-5260, (610) 337-5313,
(610) 337-5398, (610) 337-5239