



Permit to Import Infectious Biological Agents, Infectious Substances, and Vectors

In accordance with 42 CFR Section 71.54 of the Public Health Service Foreign Quarantine Regulators, cited on the bottom of this permit, permission is granted the permittee to import into any port under control of the United States, or to receive by transfer within the United States, the material described in Item 1 below.


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| PHS PERMIT NO. | 2016-08-179 | |
| DATES | ISSUED: Wednesday, October 19, 2016 | EXPIRES: Thursday, October 19, 2017 |
| 1. DESCRIPTION OF MATERIAL | <p>BLOOD/ BLOOD PRODUCTS, BODY FLUIDS, TISSUES, AND ORGANS FROM HUMANS, NON-HUMAN PRIMATES (MACACA FASCICULARIS, CALLITHRIX JACCHUS, CHLOROCEBUS SABAEUS, MACACA MULATTA, PAN TROGLODYTES, AND SAIMIRI), SQUIRRELS, AND ISOLATES THAT MAY CONTAIN MYCOBACTERIUM AFRICANUM, MYCOBACTERIUM ASIATICUM, MYCOBACTERIUM AVIUM, MYCOBACTERIUM BTANDERI, MYCOBACTERIUM BOVIS, MYCOBACTERIUM BOVIS BACILLUS CALMETTE-GUÉRIN, MYCOBACTERIUM CANNETTI, MYCOBACTERIUM CELATUM, MYCOBACTERIUM CAPRAE, MYCOBACTERIUM GASTRI, MYCOBACTERIUM GORDONAE, MYCOBACTERIUM HAEMOPHILUM, MYCOBACTERIUM INTERJECTUM, MYCOBACTERIUM INTRACELLULARE, MYCOBACTERIUM KANASASI, MYCOBACTERIUM LENTIFLAVUM, MYCOBACTERIUM MALMOENSE, MYCOBACTERIUM MARINUM, MYCOBACTERIUM MICROTI, MYCOBACTERIUM MUNGI, MYCOBACTERIUM NEBRASKENSE, MYCOBACTERIUM NONCHROMOGENICUM, MYCOBACTERIUM PARATUBERCULOSIS, MYCOBACTERIUM PINNIPEDII, MYCOBACTERIUM SCROFULACEUM, MYCOBACTERIUM SHIMOIDEI, MYCOBACTERIUM SIMIAE, MYCOBACTERIUM SZULGAI, MYCOBACTERIUM TERRAE, MYCOBACTERIUM TRIPLEX, MYCOBACTERIUM TRIVIALE, MYCOBACTERIUM TUBERCULOSIS, MYCOBACTERIUM XENOPI, MYCOBACTERIUM HASSIUM, MYCOBACTERIUM ABSCESSUS, MYCOBACTERIUM BOLLELETTII, MYCOBACTERIUM CHELONAE, MYCOBACTERIUM FLAVESCENS, MYCOBACTERIUM FORTUITUM, MYCOBACTERIUM IMMUNOGENUM, MYCOBACTERIUM GOODIE, MYCOBACTERIUM MAGERITENSE, MYCOBACTERIUM MASSILIENSE, MYCOBACTERIUM NEOAURUM, MYCOBACTERIUM PEREGRINUM, MYCOBACTERIUM PHLEI, MYCOBACTERIUM PORCINUM, MYCOBACTERIUM AFRICANUM, NOCARDIA ASTEROIDES, TSUKKAMURELLA, MYCOBACTERIUM ARUPENSE, MYCOBACTERIUM SMEGMATIS, NOCARDIA CYRIACIGEORGICA, NOCARDIA FARCINICA, NOCARDIA NOVA, HUMAN IMMUNODEFICIENCY VIRUS, AND CERCOPITHECINE HERPESVIRUS.</p> | |
| 2. PERMITTEE (NAME, ORGANIZATION, ADDRESS AND CONTACT INFORMATION) | <p>RONALD HARBECK NATIONAL JEWISH HEALTH 1400 JACKSON STREET DENVER, CO 80206</p> | <p>TEL: 303-398-1337 FAX: 303-270-2125</p> |
| 2a. OTHER AUTHORIZED PERMIT USERS | <p>VIJAYA KNIGHT NATIONAL JEWISH HEALTH 1400 JACKSON STREET DENVER, CO 80206</p> | <p>TEL: 303-398-1292 FAX: 303-270-2125</p> |
| | <p>MAX SALFINGER NATIONAL JEWISH HEALTH 1400 JACKSON STREET DENVER, CO 80206</p> | <p>TEL: 303-398-1384 FAX: 303-270-2175</p> |
| 3. SOURCE OF MATERIAL (NAME, ORGANIZATION, ADDRESS, COUNTRY) | WORLDWIDE | |
| 4. TYPE OF PERMIT AND INSTRUCTIONS FOR USE | <p>As the permittee, your facility will be subject to inspection at some time in the future to confirm that the importer's biosafety measures are commensurate with the hazard posed by the items to be imported and the level of risk given its intended use.</p> <p> <input type="checkbox"/> Single Importation into the U.S. <input checked="" type="checkbox"/> Single Transfer Within the U.S. <input checked="" type="checkbox"/> Multiple Importation into the U.S. <input type="checkbox"/> Multiple Transfer Within the U.S. </p> <p>A. Record of each importation shall be maintained on permanent file by permittee. B. Enclosed label(s) must be forwarded to the shipper(s). C. One label shall be affixed to shipping container. Enclosed labels may be photocopied.</p> | |



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| 5. CONDITIONS OF ISSUANCE ITEMS APPLICABLE WHEN CHECKED | <p><input type="checkbox"/> A. Subsequent distribution, within the U.S., of the material described in this permit is prohibited without prior authorization by the Public Health Service.</p> <p><input checked="" type="checkbox"/> B. All material is for laboratory use only - Not for use in the production of biologics for humans or animals.</p> <p><input checked="" type="checkbox"/> C. All material is free of tissues, serum and plasma of domestic and wild ruminants, swine and equines.</p> <p><input type="checkbox"/> D. Additional Requirements:</p> <p><input type="checkbox"/> IATA Packaged to preclude escape.</p> <p><input type="checkbox"/> USDA permit may be required (Telephone: 301-851-3300).</p> <p><input checked="" type="checkbox"/> E. Work with the agent(s) described shall be restricted to areas and conditions meeting requirements in the CDC/NIH publication "Biosafety in Microbiological and Biomedical Laboratories."</p> <p><input checked="" type="checkbox"/> F. Packaging must conform to 49 CFR Sections 171-180.</p> |
| | 6. Signature of Issuing officer  Samuel S. Edwin, Ph.D. Director, Division of Select Agents and Toxins |



To: Importer, Public Health Service Import Permit

Subject: Approval to import infectious biological agents, infectious substances or vectors

Attached please find your Public Health Service (PHS) import permit. The PHS import permit is valid only for the material(s), locations and conditions described in your application. Please note that the issuance and expiration dates located on the import permit pertain only to the dates that the importer is allowed to import into the United States the infectious biological agents, infectious substances, and vectors listed on the import permit. These dates do not relate to the conditions of continued possession associated with the permit. The conditions of continued possession listed on the permit remain in affect until the importer is no longer in possession of the imported material. The possession of a permit issued by the CDC does not satisfy permitting requirements placed on materials by the U.S. Department of Agriculture that may pose hazards to agriculture or agricultural production in addition to hazards to human health.

Please be reminded that the permittee must ensure that:

1. The enclosed import permit and labels are forwarded to the shipper(s). The enclosed permit and labels may be photocopied if more are needed.
2. The shipper includes the PHS import permit with the shipping documents and the enclosed label (or copy of label) should be affixed to the outer shipping container.
3. A record of each importation (including permits and shipping documents) is maintained.
4. The shipment of infectious biological agents, infectious substance or vectors must be packaged, labeled, and shipped in accordance with all applicable federal and international regulations. Please note that the issuance of an import permit is not an authorization to hand carry the material.

Please also note that other permits may be required for the importation of infectious biological agents, infectious substances or vectors. If you have questions regarding this correspondence, please contact CDC Import Permit Program at (404)718-2077 or visit our website at <http://www.cdc.gov/od/eaipp/>.

A handwritten signature in blue ink, appearing to read "Von McClee".

Von McClee, Chief, Program Services Branch
Division of Select Agents and Toxins
Department of Health and Human Services
Centers for Disease Control and Prevention

This document is intended for the exclusive use of the recipient(s) named above. It may contain sensitive information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient(s), any dissemination, distribution, or copying is strictly prohibited. If you think you have received this document in error, please notify the sender immediately and destroy the original. Thank you.



IMPORTATION OR TRANSFER AUTHORIZED BY

PHS Permit No. _____

Expiration Date _____

TO:



DO NOT OPEN INTRANSIT

**BIOMEDICAL MATERIALS
ETIOLOGICAL AGENTS OR VECTORS**

NOTICE TO CARRIER: If inspection on arrival in U.S. reveals evidence of damage, leakage, or suspected contamination involving an infectious substance, immediately notify: DOT National Response Center 1-800-424-8802.

CDC 0.1007 3/2008



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