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OMB APPROVED
0579-0015 and -0055

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES

ADDITIONAL INFORMATION FOR CELL CULTURES AND THEIR PRODUCTS

*(Monoclonal Antibodies, Recombinant Products, Extracts, Viruses, etc.)
(Supplement to VS Form 16-3)*

1. SPECIES AND TISSUE OF ORIGIN OF CELL LINE(S). ALSO, INCLUDE COUNTRY OF ORIGIN

2. IMMUNOGEN *(for monoclonal antibodies and hybridomas)*

3. REFERENCE NUMBER OF CELL LINE(S)

4. IDENTIFY ALL ANIMAL DERIVED NUTRITIVE FACTORS IN THE MEDIA *(e.g., serum, albumin, transferrin, trypsin, etc.)*. IDENTIFY THE COUNTRY OF ORIGIN AND SPECIES OF ORIGIN OF ALL NUTRITIVE FACTORS.

5. IDENTIFY ANY ANIMAL PATHOGENS THAT ARE STUDIED IN THE LAB WHERE THE CELL LINE ORIGINATES. ALSO NAME ANY ANIMAL PATHOGENS INFECTING THE CELL LINE.

6. IF THE CELL LINE IS RECOMBINANT, SPECIFY GENETIC INSERT *(do not use abbreviations)*

7. POTENTIAL USE OF IMPORTED CELLS OR PRODUCTS *(use of derivatives or extracts, immunogen for antibodies produced, and production method. If for animal use, specify the animal species.)*

8. SIGNATURE

9. DATE

Privacy Act Statement

Authority:

The Honeybee Act, 7 U.S.C. 281-286; the Plant Protection Act, 7 U.S.C. 7701-7772 and 7781-7786; and the Animal Health Protection Act, 7 U.S.C. 8301-8321.

Purpose:

This data will be used to enable persons wishing to move a regulated commodity into, from, or within the United States to apply for a permit, pay permit application fees, check the status of a permit application, and view issued permits and other information online in a secure manner.

Routine Uses:

In addition to those disclosures generally permitted under 5 U.S.C. 552a (b) of the Privacy Act, records maintained in the system may be disclosed outside USDA as follows:

1. To the Department of Homeland Security's Customs and Border Protection agency, which inspects shipments that arrive at United States ports for compliance with permit conditions;
2. To cooperative Federal, State, and local government officials, employees, or contractors, and other parties engaged to assist in administering the program. Such contractors and other parties will be bound by the nondisclosure provisions of the Privacy Act. This routine use assists the agency in carrying out the program, and thus is compatible with the purpose for which the records are created and maintained;
3. To State government regulatory officials in the State of destination for review and comment;
4. To the appropriate agency, whether Federal, State, local, or foreign, charged with responsibility of investigating or prosecuting a violation of law or of enforcing, implementing, or complying with a statute, rule, regulation, or order issued pursuant thereto, of any record within this system when information available indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and either arising by general statute or particular program statute, or by rule, regulation, or court order issued pursuant thereto;
5. To the Department of Justice when the agency, or any component thereof, or any employee of the agency in his or her official capacity, or any employee of the agency in his or her individual capacity where the Department of Justice has agreed to represent the employee, or the United States, in litigation, where the agency determines that litigation is likely to affect the agency or any of its components, is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice is deemed by the agency to be relevant and necessary to the litigation; provided, however, that in each case, the agency determines that disclosure of the records to the Department of Justice is a use of the information contained in the records that is compatible with the purpose for which the records were collected;
6. For use in a proceeding before a court or adjudicative body before which the agency is authorized to appear, when the agency, or any component thereof, or any employee of the agency in his or her official capacity, or any employee of the agency in his or her individual capacity where the agency has agreed to represent the employee, or the United States, where the agency determines that litigation is likely to affect the agency or any of its components, is a party to litigation or has an interest in such litigation, and the agency determines that use of such records is relevant and necessary to the litigation; provided, however, that in each case, the agency determines that disclosure of the records to the court is a use of the information contained in the records that is compatible with the purpose for which the records were collected;
7. To appropriate agencies, entities, and persons when the agency suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised; the agency has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, a risk of identity theft or fraud, or a risk of harm to the security or integrity of this system or other systems or programs (whether maintained by the agency or another agency or entity) that rely upon the compromised information; and the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the agency's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm;
8. To USDA contractors, partner agency employees or contractors, or private industry employed to identify patterns, trends or anomalies indicative of fraud, waste, or abuse; and
9. To the National Archives and Records Administration or to the General Services Administration for records management inspections conducted under 44 U.S.C. 2904 and 2906.

Disclosure:

Furnishing this information is voluntary; however, failure to furnish this information may impede the ability to apply for a permit.