Use of the new harmonized Form FDA 356h when fully implemented will allow a biologic product manufacturer to submit one biologic license application instead of two separate applications (product license application (PLA) and establishment license application (ELA)).

Applicants submitting an NDA, ANDA, or AADA may begin to use the new Form FDA 356h immediately. However, such applicants will be required to use the new Form FDA 356h beginning January 8, 1998. In the interim period the old Form FDA 356h, interim Form FDA 3439, and the new Form FDA 356h are all acceptable alternatives for NDA's, ANDA's, and AADA's.

For products currently submitted in the form of a biologics license application under section 351 (42 U.S.C. 262) of the PHS Act, including the biotechnology products specified in § 601.2(c), and autologous somatic cell therapy products, applicants may begin to use the new form immediately. The new Form FDA 356h will be required for products specified in § 601.2(c), and autologous somatic cell therapy products beginning January 8, 1998. Before this effective date, interim Form FDA 3439 is an acceptable alternative. Guidance documents entitled ''Guidance for Industry for the Submission of Chemistry, Manufacturing, and Controls Information for a Therapeutic Recombinant DNA-Derived Product or a Monoclonal Antibody Product for In Vivo Use'' (61 FR 56243, October 31, 1996); ''Guidance for the Submission of Chemistry, Manufacturing, and Controls Information and Establishment Description for Autologous Somatic Cell Therapy Products'' (62 FR 1460, January 10, 1997); and ''Guidance for Industry for the Submission of Chemistry, Manufacturing and Controls Information for Synthetic Peptide Substances'' (available via the CDER home page at http://www.fda.gov/CDER and select the ''Regulatory Guidance'' section) are available to assist applicants in preparing the chemistry, manufacturing, and controls (CMC) and establishment description sections of the application.

Until further notice, if the biological product is not specified in § 601.2(c) or is not an autologous somatic cell therapy product, applicants should continue to use the forms listed in this notice currently in use by CBER. For these other biological products, including vaccines, blood and blood components, in vitro diagnostic test kits used to screen the blood supply, naturally derived protein products, allergenic products, and all other biological products, a PLA and an ELA should continue to be submitted. In future **Federal Register** notices, FDA will advise applicants for the products not yet using the new Form FDA 356h, when they may voluntarily begin, and when they will be required to use the new Form FDA 356h. FDA is in the process of preparing guidance documents on the content and format of the CMC and establishment description sections of the new Form FDA 356h for those biological products not yet using the new form. As these guidance documents are completed, FDA will begin accepting the new Form FDA 356h.

The harmonized Form FDA 356h solicits information from the applicant in the following areas: (1) General applicant information, (2) product description, (3) application information, (4) establishment information, and (5) cross references to other applications. In addition, the form solicits 19 items, including information regarding labeling, CMC, nonclinical and clinical information, patent information, establishment description information, plus certifications.

II. Requests for Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the new harmonized Form FDA 356h. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

FDA will consider any comments received in determining whether revisions to the Form FDA 356th are warranted.

III. Electronic Access

An electronic version of this form is also available via Internet using the World Wide Web (WWW). For access, connect to the FDA Form Distribution Page at http://aosweb.psc.dhhs.gov/forms/fdaforms.htm.

Dated: June 30, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–17717 Filed 7–7–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of January 10, 1997 (62 FR 1462). The document was amended to reflect the realignment of the Office of Health and Industry Programs, Center for Devices and Radiological Health, Office of Operations, FDA, under part H, chapter HF (FDA) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services. The agency inadvertently omitted a paragraph from the document. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: LTonya L. Barnes, Division of Management Systems and Policy (HFA–340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4807.

In FR Doc. 97–578, appearing on page 1462 in the **Federal Register** of Friday, January 10, 1997, the following correction is made:

1. On page 1462, in the second column, a new fourth paragraph is added to read ''Manages the Staff College to develop, coordinate, and provide continuing education and training for center employees.''

Dated: June 30, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–17718 Filed 7–7–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Information Collection Submitted to the Office of Management and Budget (OMB) for Extension Approval Under the Paperwork Reduction Act

ACTION: Notice.

SUMMARY: The proposal for the collection of information listed below has been submitted to OMB for extension approval under the provisions of the Paperwork Reduction Act. Copies of the proposed information collection

requirement, related forms and explanatory materials may be obtained by contacting the Fish and Wildlife Service's Information Collection Clearance Officer at the address listed below.

DATES: Comments must be submitted on or before August 7, 1997.

ADDRESSES: Comments and suggestions on the requirement should be sent directly to the Office of Information and Regulatory Affairs, OMB, Attention: Interior Department Desk Officer, Washington, DC 20503; and a copy of the comments should be sent to the Information Collection Clearance Officer, U.S. Fish and Wildlife Service (MS 224–ARLSQ); 1849 C Street, NW., Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Phyllis H. Cook, Service Information Collection Clearance Officer, 703/358–1943; 703/358–2269 (fax).

SUPPLEMENTARY INFORMATION: Comments are invited on (1) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and, (4) ways to minimize the burden of the collection of information on respondents.

Title: Declaration for Importation or Exportation of Fish or Wildlife.

OMB Approval Number: 1018–0012.

Description and use: The Endangered Species Act (ESA) of 1972, as amended, also known as Section 9(e), makes it unlawful for any person importing or exporting fish, wildlife or plants to fail to file any person importing or exporting fish, wildlife or plants to fail to file any declaration or reports, as the Secretary deems necessary to facilitate enforcement of the Act or to meet the obligations of the Convention on International Trade in Endangered Species of Wild Flora and Flora (CITES). Importers and exporters exempt from the requirements of Section 9(e) are as follows: Persons importing or exporting shellfish and fishery products, which are not listed as endangered or threatened and are imported for the purposes of human or animal consumption or taken in waters under the jurisdiction of the United States or on the high seas for recreational purposes. Generally, these exemptions apply to persons importing or exporting wildlife products or manufactured articles, not intended for sale, as personal accompanying baggage or part of a shipment of household effect and to persons importing or exporting certain sport taken fish and wildlife. Dead, preserved, dried, or imbedded scientific specimens or parts, not requiring permits under other parts of Title 50 of the Code of Federal Regulations (CFR), imported or exported by accredited scientists or accredited scientific institutions for taxonomic or systematic research purposes may be imported or exported through any U.S. Customs port provided that a Service Form 3–177 is filed within 180 days with the appropriate Assistant Regional Director—Law Enforcement in the region where the import or export occurred.

The information collected is necessary for the Secretary of the Interior to fulfill the statutory requirements set forth for the enforcement of the ESA, including compilation of an annual report on the import and export of fish and Wildlife (a treaty obligation under CITES). Such information is used by the Service as an enforcement tool and managerial aid in monitoring the international wildlife market.

Service form number: 3–177.

Frequency: On occasion.

Description of respondents: Individuals or households; federal, state and local governments; businesses, and non-profit institutions.

Number of respondents: 81,792. (The Service estimates that 20,448 respondents will submit an average of 4 declarations annually.)

Completion time: The Service estimates that an average of 15 minutes would be required per entry.

Total annual burden: 20,448 hours.

Dated: June 23, 1997.

Robert G. Streeter,

Assistant Director—Refuges and Wildlife.

[FR Doc. 97–17685 Filed 7–7–97; 8:45 am]

BILLING CODE 4310–55–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Information Collection Submitted to the Office of Management and Budget (OMB) for Approval Under the Paperwork Reduction Act

ACTION: Notice.

SUMMARY: The collection of information listed below has been submitted to OMB for approval under the provisions of the Paperwork Reduction Act. A copy of the information collection requirement is included in this notice. Copies of and explanatory material may be obtained by contacting the Service Information Collection Clearance Officer at the address listed below.

DATES: Comments must be submitted on or before August 7, 1997.

ADDRESSES: Comments and suggestions on the requirement should be sent directly to the Office of Information and Regulatory Affairs; Office of Management and Budget; Attention: Interior Desk Officer; Washington, DC 20503; and a copy of the comments should be sent to the Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS 224–ARLSQ; 1849 C Street, NW., Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Phyllis H. Cook, Service Information Collection Clearance Officer, 703/358–1943; 703/358–2269 (fax).

SUPPLEMENTARY INFORMATION: Comments are invited on (1) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and, (4) ways to minimize the burden of the collection of information on respondents.

Title: Special Use Permit Applications on National Wildlife Refuges in Alaska (contained in the Final Rule Entitled, ''Regulations for the Administration of Special Use Permits on National Wildlife Refuges in Alaska'').

Approval Number: 1018–0014.

Service Form Number(s): 3–2001.

Description and use: The National Wildlife Refuge Administration Act (16 U.S.C. 668 dd–ee), requires that economic privileges on any National Wildlife Refuge be authorized by permit only when the activity will not be incompatible with the purposes for which the refuge was established. The Alaska National Interest Lands Conservation Act (ANILCA) provides for the disposition and use of a variety of federally owned lands in Alaska. Section 1307 of ANILCA contains two provisions concerning persons and entities who are to be given special rights and preferences with respect to providing ''visitor services'' on certain lands under the administration of the Secretary of the Interior (Secretary), in this context, units of the National Wildlife Refuge System. The term, ''visitor services,'' is defined in section 1307 as ''* * * any service made available for a fee or charge to persons who visit a conservation system unit,