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