DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95D–0415]

Guidance for Industry: Changes To An Approved Application For Specified Biotechnology and Specified Synthetic Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled, ''Guidance for Industry: Changes To An Approved Application For Specified Biotechnology and Specified Synthetic Biological Products.'' The guidance document is intended to assist manufacturers in determining which reporting mechanism is appropriate for a change to an approved license application under the final rule ''Changes To An Approved Application,'' issued elsewhere in this issue of the **Federal Register**. In a separate document also published in this issue of the **Federal Register**, FDA is announcing the availability of a guidance document entitled, ''Guidance for Industry: Changes To An Approved Application: Biological Products,'' to assist applicants in determining how they should report changes to an approved license application for biologic products other than specified biotechnology and specified synthetic biological products under the final rule. The guidance document announced in this notice revises the draft guidance entitled, ''Draft Guidance; Changes To An Approved Application for Well-Characterized Therapeutic Recombinant DNA-Derived and Monoclonal Antibody Biotechnology Products'' announced in the **Federal Register** of January 29, 1996 (61 FR 2748).

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled, ''Guidance for Industry: Changes To An Approved Application For Specified Biotechnology and Specified Synthetic Biological Products'' to the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, or Center for Drug Evaluation and Research (HFD–210), Drug Information Branch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074, or

Yuan Yuan Chiu, Center for Drug Evaluation and Research (HFD–800), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–0260.

SUPPLEMENTARY INFORMATION:

The guidance document announced in this notice represents the agency's current thinking on changes to an approved application for specified biotechnology and specified synthetic biological products listed in 21 CFR 601.2(c), recombinant DNA-derived protein/polypeptide products approved under the Federal Food, Drug, and Cosmetic Act (the act), and complexes or conjugates of a drug with a monoclonal antibody approved under the act. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments regarding the guidance document. 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. A copy of the guidance document and received comments are available for public examination in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Persons with access to the INTERNET may obtain the guidance document by using the World Wide Web (WWW), or bounce-back e-mail. For WWW access, connect to CBER at ''http://www.fda.gov/cber/cberftp.html''. To receive the guidance document by bounce-back e-mail, send a message to ''CHARACTER@a1.cber.fda.gov''.

Received comments will be considered in determining whether further revision of the guidance document is warranted.

Dated: May 28, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–19426 Filed 7–23–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95D–0052]

Guidance for Industry: Changes To An Approved Application: Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled, ''Guidance for Industry: Changes To An Approved Application: Biological Products.'' The guidance document is intended to assist manufacturers in determining which reporting mechanism is appropriate for a change to an approved application, to reduce the burden on manufacturers of reporting changes, and to facilitate the approval process. The guidance document applies to all licensed biological products and establishments, including Whole Blood, blood components, Source Plasma, and Source Leukocytes, but not including specified biotechnology and specified synthetic biological products, or products formerly referred to as well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology products. The guidance document announced in this notice revises the draft guidance entitled, ''Changes To An Approved Application; Draft Guidance,'' announced in the **Federal Register** of January 29, 1996 (61 FR 2749).

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of ''Guidance for Industry: Changes To An Approved Application: Biological Products,'' to the Office of Communication, Training and Manufacturers Assistance (HFM–40),

Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance document entitled, ''Guidance for Industry: Changes To An Approved Application: Biological Products.'' The guidance document is issued in accordance with the principles set forth in Executive Order 12866, in a continuing effort to reduce unnecessary reporting burdens on manufacturers holding licenses approved by the Center for Biologics Evaluation and Research (CBER) under section 351 of the Public Health Service Act.

As announced in the **Federal Register** of January 9, 1995 (60 FR 2351), FDA held a public meeting on January 26, 1995, as a forum for the public to voice their comments regarding CBER's retrospective review of biologics regulations. In comments made to the public docket, and at the January 26, 1995, public meeting, representatives from the biologics industry requested that FDA modify § 601.12 (21 CFR 601.12) to be more flexible and less burdensome.

FDA published the guidance document entitled, ''Changes To Be Reported for Product and Establishment License Applications; Guidance,'' in the **Federal Register** of April 6, 1995 (60 FR 17535). In a continuing effort to reduce unnecessary reporting burdens and in response to comments received on the April 6, 1995, guidance document, FDA published the proposed rule entitled, ''Changes To An Approved Application'' in the **Federal Register** of January 29, 1996 (61 FR 2739). FDA proposed to amend the biologics regulations for reporting changes to an approved application. In the same issue of the **Federal Register**, FDA announced the availability of a draft guidance document entitled, ''Changes To An Approved Application; Draft Guidance.'' The draft guidance document, issued for public comment only, set forth CBER'S interpretation of the proposed rule to amend § 601.12. In addition, FDA announced the availability of the draft guidance document entitled, ''Draft Guidance; Changes To An Approved Application For Well-Characterized Therapeutic Recombinant DNA-Derived and Monoclonal Antibody Biotechnology Products,'' which applied only to well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology products.

As announced in the **Federal Register** of March 28, 1996 (61 FR 13793), FDA held a public meeting on April 19, 1996, to discuss and gather information on the proposal to amend the biologics regulations for reporting changes to an approved application and the two closely related draft guidance documents that were made available concurrently. In comments received on the proposed rule and the draft guidance documents, representatives from the biologics industry asked that a category system of changes to be reported be implemented that would include changes that can be made without prior approval. FDA has considered all comments and developed a regulatory scheme in response to the requests.

Elsewhere in this issue of the **Federal Register**, FDA is issuing a final rule entitled, ''Changes To An Approved Application.'' In addition to the guidance document announced in this notice, FDA is announcing the availability of a guidance document entitled, ''Guidance for Industry: Changes To An Approved Application For Specified Biotechnology and Specified Synthetic Biological Products,'' that revises the draft guidance document entitled, ''Draft Guidance; Changes To An Approved Application For Well-Characterized Therapeutic Recombinant DNA-Derived and Monoclonal Antibody Biotechnology Products.''

The guidance document announced in this notice is intended to assist manufacturers in determining how a change to an approved application should be reported or documented under the revised § 601.12 for changes to a product, production process, quality controls, equipment, facilities, responsible personnel, or labeling. The guidance document lists the three-category scheme for reporting biological product changes.

The guidance document includes examples of changes to be reported under the three reporting categories applicable to all biological products, including Whole Blood, blood components, Source Plasma, and Source Leukocytes, but not including specified biotechnology and specified synthetic biological products. The ''Guidance for Industry: Changes To An Approved Application: Biological Products'' supersedes the guidance document entitled, ''Changes To Be Reported for Product and Establishment License Applications; Guidance'' (April 1995) and reflects revisions made to § 601.12 in the final rule.

As with other procedural guidance documents, FDA does not intend this guidance document to be all-inclusive. Alternative approaches might be warranted in specific situations, and certain aspects would not be applicable to all situations. If a manufacturer believes that the procedure described in this guidance document would be inapplicable to a particular product and other procedures would be appropriate for CBER's consideration, the manufacturer may wish to discuss the matter further with the agency to prevent expenditure of money and effort on activities that later may be determined to be unacceptable by FDA. CBER will continue to review submissions on a case-by-case basis.

The guidance document announced in this notice represents the agency's current thinking on changes to an approved application for all licensed biological products, except specified biotechnology and specified synthetic biological products listed in 21 CFR 601.2. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments regarding the guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and requests for copies are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance document and received comments are available for public examination in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Persons with access to the Internet may obtain the guidance document by using the World Wide Web (WWW), or bounce-back e-mail. For WWW access,

connect to CBER at ''http://www.fda.gov/cber/cberftp.html''. To receive the guidance document by bounce-back e-mail, send a message to ''CHANGES@a1.cber.fda.gov''.

Received comments will be considered in determining whether further revision of the guidance document is warranted.

Dated: May 28, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–19412 Filed 7–23–97; 8:45 am]

BILLING CODE 4160–01–F