Receipt of new/revised/ supplementary/ competitive re- newal applica- tions	Initial review	Sec- ondary review	Earliest award date
May 1, 1995	June	July	Aug. 1, 1995.

## FUTURE RECEIPT DATES ARE AS FOLLOWS:

Receipt of new/revised/ supplementary/ competitive re- newal applica- tions	Initial review	Sec- ondary review	Earliest award date
April	June	July	Aug.

## Where to Obtain Additional Information

All application procedures and guidelines are contained within this program announcement. Business management technical assistance may be obtained from Maggie Slay, Grants Management Specialist, Centers for Disease Control and Prevention (CDC), 255 East Paces, Ferry Road, NE., Mailstop E13, Atlanta, GA 30305, telephone (404) 842-6797. Programmatic technical assistance may be obtained from Tom Voglesonger, Program Manager, Injury Control Research Centers, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, Mailstop K58, Atlanta, GA 30341-3724, telephone (404) 488-4265.

Potential applicants may obtain a copy of "Healthy People 2000" (Full Report, Stock No. 017–001–00474–0) or "Healthy People 2000" (Summary Report; Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 783–3238.

Dated: February 21, 1995.

## Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

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BILLING CODE 4163-18-P

Food and Drug Administration

[Docket No. 94D-0386]

## Revised FDA Form 3210 Application for Establishment License for Manufacture of Biological Products (4/ 94); Availability

**AGENCY:** Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the revised FDA Form 3210 Application for Establishment License for Manufacture of Biological Products (4/94). This form replaces the previous edition of FDA Form 3210 (12/ 88). FDA Form 3210 is used by manufacturers to apply for licensure of a facility for the manufacture of biological products regulated under the Public Health Service Act. The form has been revised because of inadequacies in the previous form that resulted in requests by the agency for supplemental information. The revised form is intended to shorten review time and decrease expenditure of resources for both the agency and industry.

**DATES:** FDA will continue to accept submissions using the previous Form 3210 (12/88) until August 28, 1995.

FOR FURTHER INFORMATION CONTACT: Timothy W. Beth, Center for Biologics Evaluation and Research (HFM–635), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852– 1448, 301–594–3074.

ADDRESSES: Submit written requests for single copies of the revised FDA Form 3210 Application for Establishment License for Manufacture of Biological Products (4/94) to Division of Congressional and Public Affairs (HFM-11), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-1800. Requests should be identified with the docket number found in brackets in the heading of this document. Send two self-addressed adhesive labels to assist that office in processing your requests. The form may also be obtained by calling the CBER FAX Information System at 301–594-1939 from a FAX machine with a touch tone phone attached or built in. FDA Form 3210 Application for Establishment License for Manufacture of Biological Products (4/94) is available for public examination in the Dockets Managements Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD

20857, between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION: FDA is making available revised FDA Form 3210 Application for Establishment License for Manufacture of Biological Products (4/94). The form was revised due to inadequacies in the old form which made the application review process cumbersome and difficult for both the agency and industry. In the past, the review process was often significantly lengthened because of requests by the agency for supplemental information from the manufacturer in order to ensure the safety, purity, potency, and efficacy of manufactured biological products. The revised form details more specifically the information that is required for establishment licensure. FDA believes that the revised form will expedite the review process by reducing the need for supplemental information requests and responses.

The revised form solicits information from the manufacturer in the following areas: (1) General information (names and addresses); (2) water systems; (3) heating ventilation and air conditioning systems; (4) raw materials and ancillary facilities; (5) source materials; (6) propagation of host systems; (7) intermediate processing; (8) formulation and final product preparation; (9) computer systems; (10) support areas; (11) quality control areas; (12) animal facilities for testing; (13) animal facilities for production; (14) calibration and validation; and (15) records.

In addition, the revised form also requires the following information to be submitted: A description of the lot numbering system, an organizational chart, an environmental assessment report, written agreements, curriculum vitae for key manufacturing and responsible personnel, and an overview of the current good manufacturing practices (CGMP) training program. A comments section is provided on the revised form for additional information that the manufacturer deems to be appropriate but may not be covered under other sections.

Manufacturers preparing to submit applications for establishment licensure should now utilize the revised (4/94) form. FDA will continue to accept submissions using the previous (12/88) form until August 28, 1995. Because the old form does not address specific questions and issues that are present on the revised form, additional review cycles should be anticipated when using the previous form.

Under the Paperwork Reduction Act of 1980 (Pub. L. 96–511) all forms requesting a collection of information