and accomplishments characteristics, (c) better develop CBO technical assistance (TA) materials, and (d) provide TA to CBOs that have already been selected by CDC for funding. This study will also yield more hypotheses for statistical testing, instruments with reliability and validity data for use in other studies, and a model that can be used and revised to meet the context of a particular CBO. The questionnaire will be administered to 766 CBOs that have applied for CDC funding under program announcements 00023, 00100, 99047, 99091, 99092, 99096. The total annual cost to respondents is estimated at $26,044 based on an average salary of $35,000 ($17.00 per hour) for program managers.

Respondents	No. of respondents	No. of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Model Survey	766	1	2	1532
Total	.....	.....	.....	1532

Dated: February 1, 2001.

Nancy Cheal,

Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–3178 Filed 2–6–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Delegations of Authority

Notice is hereby given that on January 19, 2001 the Director of Child Support Enforcement redelegated to the Deputy Commissioner of Child Support Enforcement, all the authorities delegated to the Deputy Director/Commissioner of Child Support Enforcement by the Director of Child Support Enforcement. This delegation is subject to any limitations or conditions contained in the delegations to the Deputy Director/Commissioner.

Dated: January 19, 2001.

Olivia A. Golden,

Director, Child Support Enforcement.

[FR Doc. 01–3114 Filed 2–6–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1651]

Devices—Inspections of Medical Device Manufacturers Compliance Program Guidance Manual, CP 7382.845; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a compliance program (CP) entitled ''Inspection of Medical Device Manufacturers.'' This CP is intended to help FDA components and industry comply with FDA's internal inspection and compliance processes concerning quality system/good manufacturing practice (QS/GMP) inspections of manufacturers of medical devices.

DATES: Submit written comments on this CP at any time.

ADDRESSES: Submit written requests for single copies of CP 7382.845 ''Inspections of Medical Device Manufacturers'' to the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Copies of the CP may also be downloaded to a personal computer with access to the Internet. The Office of Regulatory Affairs (ORA) home page includes the CP and may be accessed at http://www.fda.gov/ora. The CP will be available on the compliance references page for ORA. Submit written comments on the CP to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: *Technical questions concerning inspections of medical device manufacturers:* Denise D. Dion, Division of Emergency and Investigational Operations (HFC–130), Office of Regional Operations, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5645, FAX 301–443–6919.

Questions concerning regulatory actions and all comments: Wes W. Morgenstern, Division of Program Operations (HFZ–305), Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–4699, FAX 301–594–4715.

SUPPLEMENTARY INFORMATION: FDA has renumbered CP 7382.830 as CP 7382.845 and revised it to reflect a change in the guidance on how a QS/GMP inspection of a medical device manufacturer should be conducted. The new inspectional method is known as the quality systems inspection technique. The revision to the CP also reflects changes in when FDA may consider a firm out of compliance with the medical device quality system regulation (21 CFR part 820).

The CP is intended to provide policy and regulatory guidance to FDA's field and headquarters staff with regard to medical device manufacturer inspections. It also contains information that may be useful to the regulated industry and to the public.

The CP is being issued as a guidance document and represents the agency's current thinking on the subject. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. FDA published a notice making a draft of the CP available for public comment in the **Federal Register** (64 FR 44024, August 12, 1999).

The agency has adopted good guidance practice (GGP) regulations (65 FR 56468, September 19, 2000) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents. This CP is issued as a level 1 guidance consistent with GGP's.

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the CP entitled ''Inspections of Medical Device Manufacturers'' at any time. Two copies of any comments are to be submitted, except 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 CP and

received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 22, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–3203 Filed 2–6–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1662]

Draft ''Guidance for Industry: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans'' dated February 2001. The draft guidance document is intended to provide guidance on the production, testing, and evaluation of products intended for use in xenotransplantation.

DATES: Submit written comments on the draft guidance to ensure their adequate consideration in preparation of the final document by May 8, 2001.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Guidance for Industry: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans'' dated February 2001 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. Send one self-addressed adhesive label to assist the office in processing your requests. The 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans'' dated February 2001. For the purpose of the draft guidance ''xenotransplantation'' refers to any procedure that involves the transplantation, implantation, or infusion into a human recipient of either: (1) Live cells, tissues, or organs from a nonhuman animal source, or (2) human body fluids, cells, tissues, or organs that have had ex vivo contact with live nonhuman animal cells, tissues, or organs. This document is intended to provide guidance on the production, testing, and evaluation of products intended for use in xenotransplantation. The draft guidance includes scientific questions that should be addressed by sponsors during protocol development and during the preparation of submissions to FDA (e.g., investigational new drug application and biologics license application). The topics in the draft guidance include: Regulatory responsibility; source animal and xenotransplantation products characterization; microbiological testing of xenotransplantation products; manufacturing and process-related good manufacturing practice considerations for harvest and processing of xenotransplantation products; preclinical considerations for xenotransplantation products; and clinical issues in xenotransplantation.

FDA has previously announced the availability of the guidance document entitled ''Guidance for Industry: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans'' dated April 1999, in the **Federal Register** of April 6, 1999 (64 FR 16743). FDA also announced the availability of the draft guidance document ''Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products From Xenotransplantion Product Recipients and Their Contacts'' dated December 1999, in the **Federal Register** of December 30, 1999 (64 FR 73562). In the future, FDA intends to finalize the guidance. Furthermore, FDA is considering developing draft guidance to address various issues pertaining to FDA's regulation of transgenic animals.

This draft guidance is being issued consistent with FDA's good guidance practice regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance document represents the agency's current thinking with regard to the production, testing, and evaluation of products intended for use in xenotransplantation. 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. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The draft guidance document is intended to provide information and does not set forth requirements.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Submit written comments to ensure adequate consideration in preparation of the final document by May 8, 2001. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cber/guidelines.htm.

Dated: December 26, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–3202 Filed 2–6–01; 8:45 am]

BILLING CODE 4160–01–F