In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF.

Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: February 26, 2001.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 01–5009 Filed 2–28–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1435]

Agency Information Collection Activities; Announcement of OMB Approval; Substantial Evidence of Effectiveness of New Animal Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Substantial Evidence of Effectiveness of New Animal Drugs'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 16, 2000 (65 FR 49989), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0356. The approval expires on February 29, 2004. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: February 22, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–4961 Filed 2–28–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95N–0220]

Agency Information Collection Activities; Announcement of OMB Approval; Substances Approved for Use in the Preparation of Meat and Poultry Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Substances Approved for Use in the Preparation of Meat and Poultry Products'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 25, 2000 (65 FR 51758), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0461. The approval expires on February 29, 2004. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: February 22, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–4965 Filed 2–28–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0242]

Agency Information Collection Activities; Announcement of OMB Approval; Biological Products: Reporting of Biological Product Deviations in Manufacturing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Biological Products: Reporting of Biological Product Deviations in Manufacturing'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 7, 2000 (65 FR 66621), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0458. The approval expires on February 29, 2004. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: February 22, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–4966 Filed 2–28–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0044]

Medical Devices Draft Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver.'' FDA is issuing this draft guidance to propose alternative criteria for obtaining CLIA waiver to the criteria proposed by the Health Care Financing Administration (HCFA) and the Centers for Disease Control and Prevention (CDC). This draft guidance is neither final nor in effect at this time.

DATES: Submit written comments on the draft guidance by May 30, 2001.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Joseph L. Hackett, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1243.

SUPPLEMENTARY INFORMATION:

I. Background

FDA assumes primary responsibility for performing the CLIA complexity categorization functions that includes requests for waiver. Responsibility for determining whether a particular device is waived was transferred from the CDC to FDA on January 21, 2000. At the same time, HCFA is responsible for financial management operations of the CLIA program. In the **Federal Register** of September 13, 1995 (60 FR 47534), HCFA and CDC published a notice of proposed rulemaking that proposed criteria for obtaining CLIA waiver (the 1995 proposed rule). FDA believes, based on its interpretation of the legislative history and the changes to the CLIA statute enacted by Congress on November 21, 1997, as part of the Food and Drug Administration Modernization Act of 1997 (FDAMA), that alternative criteria to the criteria proposed by HCFA and CDC can be used to determine whether a device can be waived. HCFA, CDC, and FDA are continuing to discuss whether the criteria contained in this guidance appropriately reflect the intent of the statute. In an effort to get additional perspective on these criteria, this draft guidance will be discussed at the Clinical Laboratory Improvement Advisory Committee (CLIAC) meeting to obtain their advice and recommendations. FDA is publishing this draft guidance so that it can be presented and discussed at the February 7 and 8, 2001, CLIAC meeting. FDA remains committed to ensuring an open, consistent, reliable process that all parties can understand and comment on as we take steps to finalize a rule.

Because FDA believes the agency will have to repropose a regulation to clarify waiver criteria, we think it will be some time before a final rule is codified. If this draft guidance is made final, the agency would propose alternative waiver criteria that may continue in the interim (based on comments received on this draft guidance) until a reproposal of the regulation to clarify waiver criteria is published.

II. Significance of Guidance

FDA bases the recommendations in this draft guidance document on our interpretation of the law, our review experience with CLIA complexity reviews, and our interactions with stakeholders throughout the transition of this program from CDC to FDA. One of the interactions with stakeholders was in the form of an open public workshop on August 14 and 15, 2000. We are still evaluating the comments from this workshop. We intend to reevaluate and revise this draft guidance, as circumstances warrant, based on these and future comments. The recommendations in this draft guidance are different from the recommendations made by HCFA and CDC in their 1995 proposed rule. As stated in this draft guidance, FDA will continue to review requests for waiver that follow the criteria contained in the 1995 proposed rule; however, we will also review requests for waiver that follow the criteria contained in this draft guidance document. The most significant difference between the criteria proposed by CDC and HCFA, and the criteria outlined in this draft guidance, is that this draft guidance allows studies that compare the performance of the device in the hands of untrained users with the performance of the device in the hands of laboratory professionals to demonstrate accuracy.

This draft guidance represents the agency's current thinking on criteria for obtaining CLIA waiver. 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 applicable statutes and regulations.

The agency has adopted good guidance practices regulations (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance is issued as a Level 1 draft guidance consistent with the GGP regulations.

III. Electronic Access

In order to receive the draft guidance entitled ''Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1147) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the draft document entitled ''Guidance for Clinical Laboratory Improvement Amendments