document entitled ''Points To Consider Guidance Document on Assayed and Unassayed Quality Control Material'' 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. 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 See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.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, 301–594–3084.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance, entitled ''Points to Consider Guidance Document on Assayed and Unassayed Quality Control Materials,'' complements the existing guidance document published in February 1996, entitled ''Points to Consider for Review of Calibration and Quality Control Labeling for In Vitro Devices.'' FDA believes information in this draft guidance concerning unassayed quality control materials may be useful to manufacturers making these products, even though such materials are currently exempt from premarket review. For assayed quality control materials, the intent is for this draft guidance document to eventually be cited as the basis for abbreviated 510(k)'s for processing of assayed controls.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on assayed and unassayed quality control materials. 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 statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Points To Consider Guidance Document on Assayed and Unassayed Quality Control Material'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (2231) followed by the pound sign (#). Then 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 World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH home page includes ''Points to Consider for Guidance Document on Assayed and Unassayed Quality Control Material,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''.

IV. Comments

Interested persons may, on or before May 4, 1999, submit to Docket Management Branch (address above) written comments regarding this draft guidance. 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 heading of this document. The draft guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 19, 1999.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 99–2508 Filed 2–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1224]

Guidance for Industry on FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products.'' The guidance considers the quality and quantity of data that may be adequate to add a new use to the prescribing information for a product used in the treatment of cancer. The guidance is part of an agency effort to encourage the submission of supplemental applications for new uses for approved drug and biological products. This guidance is consistent with the Food and Drug Administration Modernization Act of 1997 (the Modernization Act), which specifies that the agency will continue its efforts to encourage sponsors to submit supplemental applications for new uses for their products.

DATES: Written comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' or ''http://www.fda.gov/cber/guidelines.htm''. Submit written requests for single copies of this guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Robert L. Justice, Center for Drug

Evaluation and Research (HFD–150), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2473.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 21, 1997 (62 FR 13650), FDA published a draft guidance for industry entitled ''Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products'' as part of efforts to encourage the submission of supplemental applications for drug and biological products. The intent of that draft guidance was to clarify what clinical evidence of effectiveness should be provided in new drug applications and supplemental applications. On that same date, the agency published a draft guidance for industry entitled ''FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products,'' which considered the quality and quantity of data that may be adequate to add a new use to the prescribing information for a product used in the treatment of cancer. These guidances were published as part of agency efforts to expedite the development of new and supplemental uses for drug and biological products.

In November 1997, the Modernization Act (Pub. L. 105–111) was signed into law by the President. Section 403 of the Modernization Act specifies that FDA will continue its efforts to encourage sponsors to submit supplemental applications for new uses for their products. Consistent with section 403 of the Modernization Act, the agency has finalized the draft guidances it issued in March 1997. After considering comments submitted by the public, FDA announced the availability, in final form, of the guidance entitled ''Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products'' in the **Federal Register** of May 15, 1998 (63 FR 27093).

This notice announces the availability of the final version of the guidance entitled ''FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products.'' This guidance focuses on the particular information to be provided when submitting an application for the approval of a supplemental new cancer treatment use for a marketed drug or therapeutic biological product. Cancer research often reveals potential new uses for already marketed drugs, and it is important to have new uses approved for inclusion in the product labeling as soon as adequate evidence of product safety and effectiveness for the new use becomes available.

Consistent with section 403(c) of the Modernization Act, CDER and CBER have designated key persons who will: (1) Encourage the prompt review of supplemental applications for approved products, and (2) work with sponsors to facilitate the development and submission of data to support supplemental applications.

Within CDER, the Associate Director for Medical Policy is fulfilling the requirements of section 403(c) of the Modernization Act by working with sponsors to facilitate the development of supplemental applications. Within the Division of Oncology Drug Products, the Special Assistant to the Division Director is working with sponsors to facilitate the development and submission of data to support supplemental applications for drug products used in cancer treatment. Efforts include: (1) Managing initiatives to seek the views of major groups and of individuals in the cancer research and treatment community, (2) managing and monitoring actions regarding possible labeling revisions, and (3) preparing regular progress reports.

Within CBER, supplemental applications are being facilitated by the Deputy Director, Medical, in accordance with section 403(c) of the Modernization Act. Review activities for most oncologic product applications are managed by the Office of Therapeutics Research and Review. The Oncology Branch of the Division of Clinical Trials Design and Analysis will work with sponsors to facilitate the development and submission of data to support supplemental applications for biologics used in cancer treatment.

This guidance represents the agency's current thinking on new cancer treatment uses for marketed drug and biological products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public in any way. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Dated: January 27, 1999.

Jane E. Henney,

Commissioner of Food and Drugs.

[FR Doc. 99–2562 Filed 2–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0375]

Guidance for Staff, Industry and Third Parties: Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Guidance for Staff, Industry and Third Parties: Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA).'' Under the Sectoral Annex on Medical Devices (Annex), FDA has agreed to designate conformity assessment bodies (CAB's) as third parties (i.e., organizations outside of FDA) authorized to perform premarket and quality system evaluations consistent with the Annex. This guidance will assist those who are interested in participating in this program as CAB's or as applicants pursuing premarket and quality system evaluations consistent with the Annex.

DATES: Written comments may be submitted at any time.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. If you do not have access to the World Wide Web, submit written requests for single copies of the guidance entitled ''Guidance for Staff, Industry and Third Parties: Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA)'' on 3.5″ diskette 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. Written comments concerning this guidance may be submitted at any time to the contact person listed below.

FOR FURTHER INFORMATION CONTACT: John F. Stigi, Division of Small Manufacturers Assistance (HFZ–220),