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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98 D-1232]

Points To Consider Guidance Document on Assayed and Unassayed Quality Control Material; Draft; 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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Points To Consider Guidance Document on Assayed and Unassayed Quality Control Material." This draft guidance is neither final nor is it in effect at this time. This draft guidance is intended to provide assistance to manufacturers of in vitro diagnostic quality control materials. It complements the existing guidance on labeling of these devices entitled "Points to Consider for Review of Calibration and Quality Control Labeling for In Vitro Diagnostic Device."

DATES: Written comments concerning this draft guidance must be received by *(insert date 90 days after date of publication in the Federal Register)*.

ADDRESSES: Written comments concerning this draft guidance must be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Points To Consider Guidance Document on Assayed and Unassayed Quality Control Material" to the Division of Small Manufacturers Assistance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 See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.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This draft guidance, entitled “Points to Consider Guidance Document on Assayed and Unassayed Quality Control Materials,” complements the existing guidance document published in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 5 10(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 (223 1) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

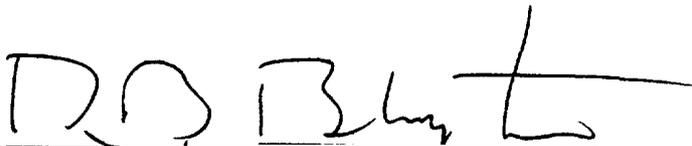
Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular 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 (*insert date 90 days after date of publication in the Federal Register*), 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: 1-19-99
January 19, 1999



D.B. Burlington
Director
Center for Devices and Radiological Health

fl [FR Doc. 98-⁹???? Filed ??-??-9⁹; 8:45 am]

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