DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0336]

Draft Guidance for Industry and Food and Drug Administration Staff; Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions.'' This guidance document is intended to clarify the regulations regarding ASRs and the role and responsibilities of ASR manufacturers.

DATES: Submit written or electronic comments on this draft guidance by [*insert date 90 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Courtney C. Harper, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0490.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is providing this guidance in order to eliminate confusion regarding particular marketing practices among ASR manufacturers. ASRs are the building blocks of laboratory-developed tests and are defined and classified in a rule codified at § 864.4020 (21 CFR 864.4020). With this draft guidance document, FDA seeks to advise ASR manufacturers that it views certain practices as being inconsistent with the marketing of an ASR, as defined in § 864.4020. Some manufacturers have believed that when they combine a Class I ASR, which is exempt from premarket notification requirements under section 510(l) of the Federal Food, Drug, and Cosmetic Act (the act), (21 U.S.C. 360(l)), with other products, or with instructions for use in a specific test, the product remains exempt because of the presence of an ASR. However, as explained in this draft guidance, when an ASR is marketed in certain ways, FDA views the product as no longer being an ASR within the meaning of § 860.4020.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized will represent the agency's current thinking on commercially distributed ASRs. 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 and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive ''Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions, '' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1590 to identify the guidance you are requesting.

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 device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 807.87 have been approved under OMB control number 0910–0120; the collections of information in 21 CFR 809.10 and 809.30 (§ 809.30) have been approved under OMB control number 0910–0485; and the collections of information in 21 CFR 814.20 have been approved under OMB control number 0910–0231.

The draft guidance includes discussion of the restrictions on the sale, distribution, and use of ASRs (§ 809.30). Under this regulation, a laboratory that develops an in-house test using an ASR must add a disclaimer when reporting the test result to the practitioner (§ 809.30(e)). Advertising and promotional materials for ASRs must not make any statement regarding analytical or clinical performance (§ 809.30(d)(4)). In addition, the labeling for Class I, exempt ASRs must bear the statement, ''Analyte Specific Reagent. Analytical and performance characteristics are not established.'' Class II or III ASRs must bear the statement, ''Analyte Specific Reagent. Except as a component of the approved/cleared test (name of approved/cleared test), analytical and performance characteristics are not established'' (§ 809.30(d)(2) and (d)(3)). The disclaimer and these statements do not constitute ''collections of information'' under the PRA. Rather, they are ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

V. Comments

Interested persons may submit to the Division of Dockets Managment (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are

to be identified with the docket number found in brackets in the heading of this document. Recieved comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 1, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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