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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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**Guidance for Industry and Food and Drug Administration Staff;
Commercially Distributed Analyte Specific Reagents: 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 guidance entitled "Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions." FDA is issuing this guidance to clarify the regulations regarding commercially distributed ASRs and the role and responsibilities of ASR manufacturers. The draft of this guidance was issued September 7, 2006.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

Manufacturers should ensure their Class II or Class III in vitro diagnostic devices, that are currently inappropriately labeled and marketed as ASRs, comply with the law by *[insert date 12 months 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

Ch0732 2006D-0336

NAD 2

Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850 or to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your request, or fax your request to 240-276-3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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 either <http://www.fda.gov/dockets/ecomments> or <http://www.regulations.gov>. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Courtney Harper, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240-276-0694.

For further information concerning the guidance as it related to devices regulated by CBER: Martin Ruta, Center for Biologics Evaluation and Research (HFM-300), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-3518.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is providing this guidance in order to minimize confusion regarding particular marketing practices pertaining to ASRs. The guidance is not

intended to cover the role of clinical laboratories in the development of laboratory developed tests. As noted in this guidance document, ASRs are building blocks of laboratory developed tests. With this final guidance document, FDA seeks to advise ASR manufacturers that it views certain practices as being inconsistent with the marketing of an ASR, as defined under § 864.4020 (21 CFR 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 (21 U.S.C. 360(l)), with other products, or with instructions for use in a specific test, the product may still be regarded as an ASR that retains class I exempt status because the product contains an ASR. However, as explained in this guidance, when an ASR is marketed in combination with other products, with instructions for use, or with specific claims, FDA views the product as no longer being an ASR within the meaning of § 864.4020. Instead, FDA views products marketed in this way as another type of in vitro diagnostic device (IVD) or device component not covered by the ASR regulations and, therefore, not necessarily exempt from premarket notification.

The draft of this guidance was published in the **Federal Register** of September 7, 2006 (71 FR 52799). FDA received and considered more than 30 sets of comments on the draft guidance document. After taking the comments into consideration, FDA has revised the draft document to provide clarifications as needed. This includes clarifying that FDA views ASRs as being intended to detect a single ligand or target. This guidance further clarifies that oligonucleotide primer pairs and polyclonal antibodies can meet the definition of an ASR when properly marketed because they are for the identification of a single target or ligand (e.g., used to detect a single protein, a single nucleotide

change, a single epitope). In addition, FDA has clarified that where manufacturers provide laboratories with information describing the use of their product in a specific test, the manufacturer's product would fall outside the definition of an ASR.

In order to assist manufacturers of Class II or III IVDs that are currently being inappropriately labeled and marketed as ASRs to come into regulatory compliance, FDA intends to exercise enforcement discretion with respect to premarket approval and clearance requirements for 12 months (see **DATES**). Manufacturers should ensure their products comply with the law by (see **DATES**).

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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 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 CBER Internet site at <http://www.fda.gov/cber/guidelines.htm> or on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

IV. Paperwork Reduction Act of 1995

This 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 part 807, subpart E 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; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437; the collections of information in 21 CFR 807.22 and 807.31(e) are approved under OMB control number 0910–0387; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; and the collections of information in 21 CFR 814.20 have been approved under OMB control number 0910–0231.

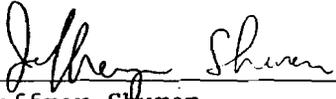
In addition, the labeling for Class I, exempt ASRs must bear the statement, “Analyte Specific Reagent. Analytical and performance characteristics are not established.” Class II or III ASRs must bear the statement, “Analyte Specific Reagent. Except as a component of the approved/cleared test (name of 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 Management (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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 9/10/2007
September 10, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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