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This draft guidance refers to previously approved collections of information found in FDA regulations.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 807.90 have been approved under OMB control number 0910–0120; the collections of information in 21 CFR 809.30 (§ 809.30) 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The draft guidance includes discussion of the restrictions on the sale, distribution, and use of ASRs (§ 809.30).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 Management (see ADDRESSES), written or electronic comments regarding this draft guidance. 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: September 1, 2006.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 06–7500 Filed 9–5–06; 4:00 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0347]

Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays; 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 “Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays.” This draft guidance addresses the definition and regulatory status of a class of in vitro diagnostic devices referred to as In Vitro Diagnostic Multivariate Index Assays (IVDMIAs). The guidance also addresses premarket and postmarket requirements with respect to IVDMIAs. An IVDMA employs data, derived in part from one or more in vitro assays, and an algorithm that usually, but not necessarily, runs on software, to generate a result that diagnoses a disease or condition or is used in the cure, mitigation, treatment, or prevention of disease.
also, as stated previously, FDA decided to exclude laboratory-developed tests from the ASR rule due to its confidence in high-complexity laboratories’ ability to use ASRs. The manufacture of an IVDMI involves steps that are not synonymous with the use of ASRs and that are not within the ordinary “expertise and ability” of laboratories that FDA referred to when it issued the ASR rule. Therefore, IVDMIs do not fall within the scope of laboratory-developed tests over which FDA has generally exercised enforcement discretion. FDA intends to issue guidance regarding those laboratory-developed tests over which it has in the past generally exercised, and over which it intends to continue to exercise, enforcement discretion. IVDMIs must meet pre- and postmarket device requirements under the act and FDA regulations, including premarket review requirements in the case of class II and III devices.

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 IVDMIs. 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 “Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays,” you may either send an e-mail request to dsmina@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 1610 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.


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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: September 1, 2006.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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