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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0530]

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Certifier A Corbin

**Draft Guidance for Industry on Tropical Disease Priority Review Vouchers;  
Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Tropical Disease Priority Review Vouchers.” There has been significant outside interest in FDA’s interpretation of section 1102 of the Food and Drug Administration Amendments Act (FDAAA), which adds a new section 524 to the Federal Food, Drug, and Cosmetic Act (the act). Section 524 makes provisions for awarding priority review vouchers for future applications to sponsors of tropical disease product applications that meet the criteria specified by the act. This draft guidance explains to internal and external stakeholders how FDA intends to implement the provisions of section 524.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by *[insert date 60 days after date of publication in the Federal Register]*. Submit written comments on the proposed collection of information by *[insert date 60 days after date of publication in the Federal Register]*.

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**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002, or 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 that office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:**

David Roeder, Office of Antimicrobial Products, Center for Drug Evaluation and Research, Food and Drug Administration (WO–22), rm. 6410, 0903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–0799, or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “Tropical Disease Priority Review Vouchers.” Section 1102 of FDAAA adds

new section 524 to the act. Section 524 is designed to encourage development of new drug or biological products for prevention and treatment of certain tropical diseases affecting millions of people throughout the world. By enacting section 524, Congress intends to stimulate new drug development for drugs to treat certain tropical diseases for which there are no or few available treatments by offering additional incentives for obtaining FDA approval for pharmaceutical treatments for these diseases. Under section 524, a sponsor of a human drug application for a qualified tropical disease may be eligible for a voucher that can be used to obtain a priority review for any application submitted under section 505(b)(1) of the act or section 351 of the Public Health Service (PHS) Act. The draft guidance also provides information on using the priority review vouchers and on transferring priority review vouchers to other sponsors.

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 obtaining tropical disease priority review vouchers. 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 statutes and regulations.

## **II. Paperwork Reduction Act of 1995**

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information that they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the

public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal agencies to provide a 60-day notice in the **Federal Register** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this draft guidance, FDA invites comments on the following topics: (1) Whether the proposed information collected is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimated burden of the proposed information collected, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of information collected on the respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Under the draft guidance, sponsors of certain tropical disease drug product applications submitted under section 505(b)(1) of the act and section 351 of the PHS Act may request a priority review voucher. Based on the inquiries FDA has received on section 524 and related discussions with sponsors, we estimate that we will receive annually approximately five requests from five sponsors, and that each request will take approximately 8 hours to prepare and submit to FDA.

The draft guidance also states that sponsors should notify FDA of their intent to use a priority review voucher, including the date on which the sponsor intends to submit the application, at least 1 year before use. We

estimate that we will receive annually approximately five notifications of intent to use a voucher from five sponsors, and that each notification will take approximately 8 hours to prepare and submit to FDA.

The draft guidance also permits the transfer of a priority review voucher from one sponsor to another, and states that each transfer should be documented with a letter of transfer. We estimate that we will receive approximately two letters indicating the transfer of a voucher from two application holders, and two letters from two new voucher owners acknowledging the transfer, and that it will take approximately 8 hours to prepare and submit each letter to FDA.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Reporting Under Section 1102 of FDAAA	No. of Respondents	No. responses per Respondent	Total Responses	Hours Per Response	Total Hours
Priority review voucher request	5	1	5	8	40
Notifications of intent to use a voucher	5	1	5	8	40
Letters indicating the transfer of a voucher	2	1	2	8	16
Letters acknowledging the receipt of a transferred voucher.	2	1	2	8	16
Total					112

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

### III. 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System

(FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: 10/1/08  
October 1, 2008.

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Jeffrey Shuren,  
Associate Commissioner for Policy and Planning.

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**BILLING CODE 4160-01-S**

**CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL**



A handwritten signature in black ink, appearing to read 'Shuren', is written over a horizontal line.