

DMPB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D-0182]

4-11-05  
4-12-05  
J. Cooke

**Guidance for Industry and Food and Drug Administration Staff; Submission and Resolution of Formal Disputes Regarding the Timeliness of Premarket Review of a Combination Product; Availability**

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

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry and FDA staff entitled "Submission and Resolution of Formal Disputes Regarding the Timeliness of Premarket Review of a Combination Product." The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) delegates to the Office of Combination Products (OCP) responsibility for resolving disputes about the timeliness of premarket review of combination products. This guidance document provides information about presenting requests for resolution of disputes about the timeliness of premarket review of combination products.

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

**ADDRESSES:** Submit written requests for single copies of this guidance document to the Office of Combination Products (HFG-3), 15800 Crabbs Branch Way, Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments

concerning the 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>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Suzanne O'Shea, Office of Combination Products (HFG-3), Food and Drug Administration, 15800 Crabbs Branch Way, Rockville, MD 20855, 301-427-1934, FAX: 301-427-1935.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance for industry and FDA staff entitled "Submission and Resolution of Formal Disputes Regarding the Timeliness of Premarket Review of a Combination Product." In the **Federal Register** of May 4, 2004 (69 FR 24653), FDA issued a notice of availability of a draft guidance document covering the same topic. The draft guidance document was entitled "Combination Products, Timeliness of Premarket Reviews, Dispute Resolution Guidance."

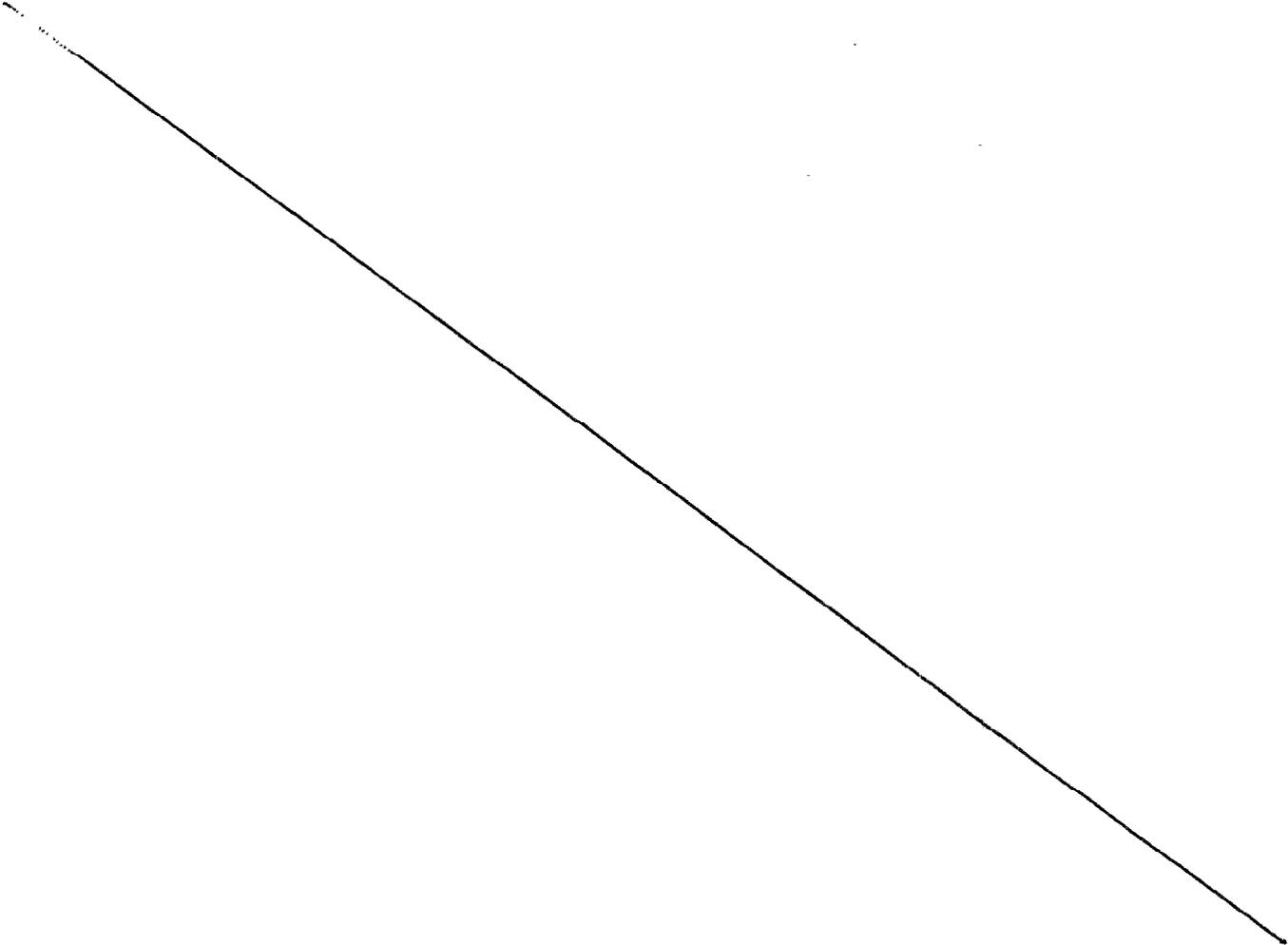
MDUFMA delegated to OCP responsibility for resolving disputes about the timeliness of reviews of premarket applications covering combination products. This guidance document provides information on how an applicant submitting an application covering a combination product can submit a request that OCP resolve such a dispute.

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 how to present to OCP disputes pertaining to the timeliness of reviews of combination products. 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.

## **II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments on the guidance at any time. Submit two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

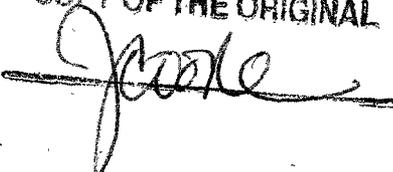


**III. Electronic Access**

Additional copies of this guidance are available at <http://www.fda.gov/oc/combo> or <http://www.fda.gov/ohrms/dockets/default.htm>. You may also request additional copies of the guidance by e-mailing [combo@fda.gov](mailto:combo@fda.gov).

Dated: 4/5/05  
April 5, 2005.

  
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Jeffrey Shuren,  
Assistant Commissioner for Policy.

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[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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