

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005M-0005]

Medical Devices Regulated by the Center for Biologics
Evaluation and Research; Availability of Safety and
Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved by the Center for Biologics Evaluation and Research (CBER). This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and FDA's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please include the appropriate docket number as listed in table 1 of this document when submitting a written request. See the SUPPLEMENTARY INFORMATION section for electronic access to the summaries of safety and effectiveness data.

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Certifier L. CLAWSON

DDM

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6-3-05

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary,
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

In the FEDERAL REGISTER of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the FEDERAL REGISTER, providing instead to post this information on the Internet at <http://www.fda.gov>. In addition, the regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during the quarter. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the FEDERAL REGISTER, and FDA believes that the Internet is accessible to more people than the FEDERAL REGISTER.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving,

denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting administrative reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The following is a list of PMAs approved by CBER for which summaries of safety and effectiveness were placed on the Internet from October 1, 2004, through December 31, 2004. There were no denial actions during the period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

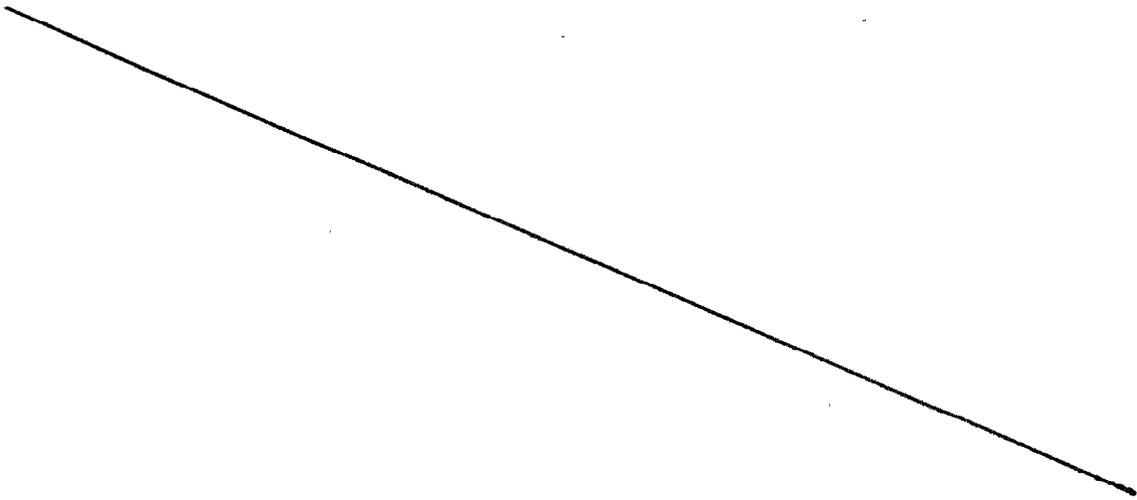


TABLE 1.--LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE
OCTOBER 1, 2004, THROUGH DECEMBER 31, 2004

PMA No./Docket No.	Applicant	Trade Name	Approval Date
BP 040046/02005M-0005	Bio-Rad Laboratories	Multispot HIV-1/HIV-2 Rapid Test	November 12, 2004

II. Electronic Access

Persons with access to the Internet may obtain the documents at <http://www.fda.gov/cber/products.htm>.

Dated: 2/11/05
April 11, 2005.

Jesse Goodman

Jesse Goodman,
Director,
Center for Biologics Evaluation and Research.

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

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