

Dated: August 20, 2007.
Jeffrey Shuren,
Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2007M-0244 and 2007M-0263]

Medical Devices Regulated by the Center for Biologics Evaluation and Research; Availability of Summaries of Safety and Effectiveness Data 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 through the Internet and FDA's Division of Dockets Management of summaries of safety and effectiveness data of approved PMAs.

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.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, suite 200N, 1401 Rockville Pike, 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 data were placed on the Internet from April 1, 2007, through June 30, 2007. There were no denial actions during this 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 SUMMARIES OF SAFETY AND EFFECTIVENESS DATA FOR APPROVED PMAS MADE AVAILABLE APRIL 1, 2007, THROUGH JUNE 30, 2007

| PMA No./Docket No. | Applicant | Trade name | Approval date |
|-----------------------|-------------------------------|--|---------------|
| BP060002/0/2007M-0244 | Abbott Molecular, Inc. | Abbott RealTime HIV-1 Amplification Reagent Kit, Abbott RealTime HIV-1 Calibrator Kit, and Abbott RealTime HIV-1 Control Kit | May 11, 2007 |
| BP050069/0/2007M-0263 | Roche Molecular Systems, Inc. | COBAS AmpliPrep/COBAS Taqman HIV-1 Test, 48 Tests, COBAS Ampliprep/COBAS Taqman Wash Reagent, 5.1.L | May 11, 2007 |

II. Electronic Access

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

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Jeffrey Shuren,
Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1999D-1878 (formerly Docket No. 99D-1878)]

“Guidance for Industry: ‘Lookback’ for Hepatitis C Virus (HCV): Product Quarantine, Consignee Notification, Further Testing, Product Disposition, and Notification of Transfusion Recipients Based on Donor Test Results Indicating Infection with HCV;” Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled “Guidance for Industry: ‘Lookback’ for Hepatitis C Virus (HCV): Product Quarantine, Consignee Notification, Further Testing, Product Disposition, and Notification of Transfusion Recipients Based on Donor Test Results Indicating Infection with HCV,” dated August 2007. The guidance document provides recommendations for complying with the HCV “Lookback” requirements. This guidance document finalizes the guidance entitled, “Draft Guidance for Industry: Current Good Manufacturing Practice for Blood and