

employment continued to expand through July and the civilian unemployment rate was unchanged at 4.5 percent. Industrial production declined considerably in June and July; most of the drop over the two months reflected the GM strike. A decline in total retail sales in July was more than accounted for by a sharp contraction in spending for motor vehicles. Residential sales and construction have remained exceptionally strong in recent months. Available indicators point to continued growth in business capital spending, although apparently at a more moderate pace than earlier in the year. Business inventory accumulation slowed sharply in the spring. The nominal deficit on U.S. trade in goods and services widened substantially further in the second quarter. Trends in wages and prices have remained stable in recent months.

Most interest rates have fallen slightly on balance since the meeting on June 30-July 1. Share prices in U.S. equity markets have remained volatile and major indexes have declined appreciably on balance over the intermeeting period. In foreign exchange markets, the trade-weighted value of the dollar rose somewhat further over the intermeeting period in relation to other major currencies; in addition, it was up slightly in terms of an index of the currencies of the developing countries of Latin America and Asia that are important trading partners of the United States.

After robust growth in the second quarter, M2 decelerated somewhat and M3 was about unchanged in July. For the year through July, both aggregates rose at rates well above the Committee's ranges for the year. Expansion of total domestic nonfinancial debt appears to have moderated somewhat in recent months after a pickup earlier in the year.

The Federal Open Market Committee seeks monetary and financial conditions that will foster price stability and promote sustainable growth in output. In furtherance of these objectives, the Committee reaffirmed at its meeting on June 30-July 1 the ranges it had established in February for growth of M2 and M3 of 1 to 5 percent and 2 to 6 percent respectively, measured from the fourth quarter of 1997 to the fourth quarter of 1998. The range for growth of total domestic nonfinancial debt was maintained at 3 to 7 percent for the year. For 1999, the Committee agreed on a tentative basis to set the same ranges for growth of the monetary aggregates and debt, measured from the fourth quarter of 1998 to the fourth quarter of 1999. The behavior of the monetary aggregates

will continue to be evaluated in the light of progress toward price level stability, movements in their velocities, and developments in the economy and financial markets.

In the implementation of policy for the immediate future, the Committee seeks conditions in reserve markets consistent with maintaining the federal funds rate at an average of around 5-1/2 percent. In the context of the Committee's long-run objectives for price stability and sustainable economic growth, and giving careful consideration to economic, financial, and monetary developments, a slightly higher federal funds rate or a slightly lower federal funds rate would be acceptable in the intermeeting period. The contemplated reserve conditions are expected to be consistent with moderate growth in M2 and M3 over coming months.

By order of the Federal Open Market Committee, October 7, 1998.

Donald L. Kohn,

Secretary, Federal Open Market Committee.

[FR Doc. 98-27737 Filed 10-15-98; 8:45 am]

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FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 10:00 a.m., Wednesday, October 21, 1998.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any matters carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Lynn S. Fox, Assistant to the Board; 202-452-3204.

SUPPLEMENTARY INFORMATION: You may call 202-452-3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at <http://www.federalreserve.gov> for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: October 14, 1998.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 98-27912 Filed 10-14-98; 10:40 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 77N-0240]

Erythrityl Tetranitrate; Drug Efficacy Study Implementation; Withdrawal of Approval of Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing conditional approval of abbreviated new drug applications (ANDA's) for single-entity drug products containing erythrityl tetranitrate. FDA is withdrawing approval because there is a lack of substantial evidence that these drugs are effective for indications relating to the management, prophylaxis, or treatment of anginal attacks.

EFFECTIVE DATE: November 16, 1998.

ADDRESSES: Requests for an opinion on the applicability of this notice to a specific product should be identified with Docket No. 77N-0240 and reference number DESI 1786 and directed to the Division of Prescription Drug Compliance and Surveillance (HFD-330), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT: Mary E. Catchings, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of June 23, 1998 (63 FR 34188), FDA revoked the temporary exemption for the drug products described in this document which permitted these products to remain on the market beyond the time limits scheduled for implementation of the Drug Efficacy Study. The notice also offered an opportunity to request a hearing on a proposal to withdraw approval of the conditionally approved new drug applications for these products insofar as they provide for indications relating

to the management, prophylaxis, or treatment of anginal attacks. The proposal was based on a lack of substantial evidence of effectiveness as required by section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) and 21 CFR 314.126.

Neither the holder of the conditionally approved ANDA's nor any other person filed a written notice of appearance and request for hearing as provided by the notice (63 FR 34188). The failure to file such an appearance and request for hearing constitutes a waiver of the opportunity for hearing. Accordingly, approval of the following conditionally approved ANDA's is being withdrawn:

1. ANDA 86-194; Cardilate Chewable Tablets containing 10 milligrams (mg) erythryl tetranitrate per tablet; Glaxo Wellcome (formerly Burroughs Wellcome), 3030 Cornwallis Rd., P.O. Box 12700, Research Triangle Park, NC 27709-2700.

2. ANDA 86-203; Cardilate Tablets containing 5, 10, or 15 mg of erythryl tetranitrate per tablet; Glaxo Wellcome.

Although FDA withdrew approval of ANDA 86-194 in the **Federal Register** of February 13, 1996 (61 FR 5563), based on the applicant's written request, this notice constitutes FDA's final conclusions on the effectiveness of the product.

Any drug product that is identical, related, or similar to the drug products named previously and is not the subject of an approved new drug application is covered by the applications listed previously and is subject to this notice (21 CFR 310.6). Any person who wishes to determine whether a specific product is covered by this notice should write to the Division of Prescription Drug Compliance and Surveillance (address above).

The Director of the Center for Drug Evaluation and Research, under section 505 of the act and under authority delegated to her (21 CFR 5.82), finds that, on the basis of new information on the drugs and the evidence available when the applications were approved, there is a lack of substantial evidence that the products named previously will have the effects they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling.

Therefore, based on the foregoing finding, approval of ANDA's 86-194 and 86-203 and all their amendments and supplements are withdrawn effective November 16, 1998. Shipment in interstate commerce of these products or of any identical, related, or similar product that is not the subject of a fully

approved new drug application will then be unlawful.

Dated: September 25, 1998.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 98-27739 Filed 10-15-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D-0530]

FDA Modernization Act of 1997: Modifications to the List of Recognized Standards; Availability; Withdrawal of Draft Guidance "Use of IEC 60601 Standards; Medical Electrical Equipment"

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the publication of the modifications to the list of standards that will be recognized for use in the premarket review process and withdrawing its draft guidance entitled "Use of IEC 60601 Standards; Medical Electrical Equipment." This will assist manufacturers who elect to declare conformity with consensus standards to meet all or part of medical device review requirements.

DATES: This recognition of standards is effective on November 16, 1998; however, written comments concerning this notice may be submitted at any time.

ADDRESSES: Submit written requests for single copies of "Modifications to the List of Recognized Standards" to the Division of Small Manufacturers Assistance (DSMA), Center for Devices and Radiological Health (HFZ-220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301-443-8818. Written comments concerning this document must be submitted to the contact person listed below. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance. This document may also be accessed via the Internet at FDA's web site "http://www.fda.gov/cdrh".

FOR FURTHER INFORMATION CONTACT: To comment on this document and/or to recommend additional standards for recognition: James J. McCue, Jr., Center for Devices and Radiological Health (HFZ-101), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-4766, ext. 137.

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105-115, 111 Stat. 2296 (1997)) amends section 514 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360d), allowing the agency to recognize consensus standards established by international and national standards development organizations that may be used to satisfy identified portions of device premarket review submissions or other requirements. In a previous notice published in the **Federal Register** of February 25, 1998 (63 FR 9561), FDA announced the availability of a guidance document entitled "Recognition and Use of Consensus Standards," which describes how FDA will implement that part of FDAMA, and provided the initial list of recognized standards (the February 1998 notice). This document announces modifications to the list of consensus standards to be recognized for use by FDA.

II. Recognition and Use of IEC 60601 Standards

In the **Federal Register** of January 13, 1998 (63 FR 1974), FDA published a notice that announced the availability of a draft guidance entitled "Use of IEC 60601 Standards; Medical Electrical Equipment" (the January 1998 notice). The purpose of the draft was to provide guidance to the Office of Device Evaluation reviewers on the use of the International Electrotechnical Commission (IEC) 60601 series of standards, including declarations of conformity to the standards, during the evaluation of premarket submissions for electrical medical devices.

FDA has decided not to finalize this draft guidance document. Instead, recognition of the IEC 60601 standards will occur by listing in this publication "Modifications to the List of Recognized Standards." There appears to be little, if any, benefit to finalizing guidance on FDA's use of IEC 60601 standards in a separate document from the general recognition of consensus standards under FDAMA, announced in the February 1998 notice, especially as there is a fair amount of overlap between the two documents.