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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: *(Insert date 30 days after date of publication in the Federal Register.)*

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

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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) erythrityl 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 erythrityl tetranitrate per tablet; Glaxo Wellcome.

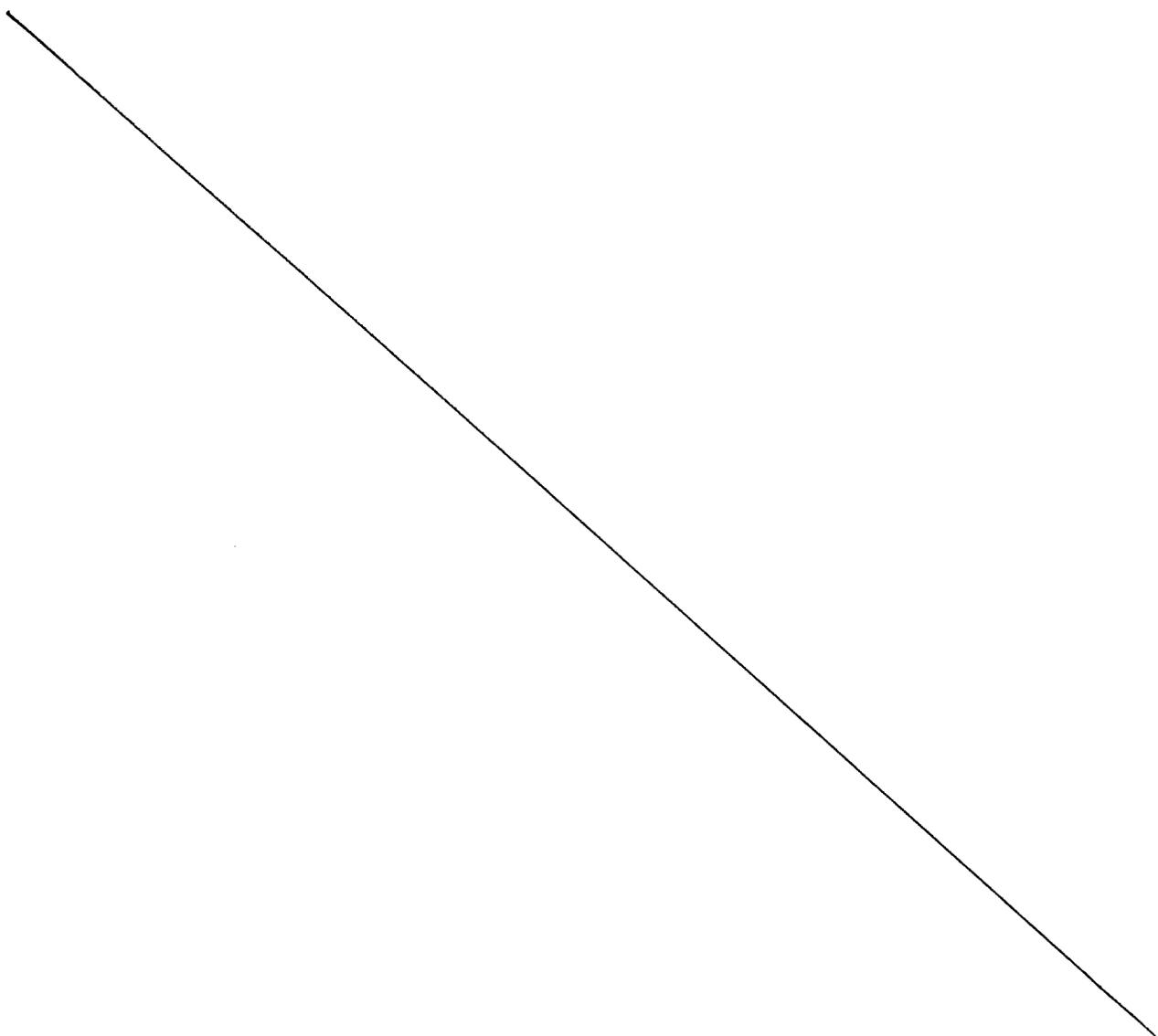
Although FDA withdrew approval of ANDA 86-194 in the **Federal Register** of February 13, 1996 (61 FR 5563), based on the applicant's written request, this notice constitutes FDA's final conclusions on the effectiveness of the product.

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

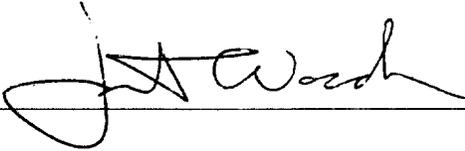
substantial evidence that the products named previously will have the effects they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling.

Therefore, based on the foregoing finding, approval of ANDA's 86-194 and 86-203 and all their amendments and supplements are withdrawn effective (*insert date 30 days after date of publication in the **Federal Register***). 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: SEP 25 1998



Janet Woodcock
Director
Center for Drug Evaluation and Research

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