

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 01P-0245]

DMB

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Certifier	<i>[Signature]</i>

**Determination That Disulfiram Tablets, 250 and 500 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness**

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

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) has determined that disulfiram (Antabuse) 250- and 500-milligram (mg) tablets, formerly marketed by Wyeth Ayerst Pharmaceuticals (Wyeth Ayerst), were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) for disulfiram drug products, and it will allow FDA to continue to approve ANDAs for disulfiram 250- and 500-mg tablets.

**FOR FURTHER INFORMATION CONTACT:** Mary E. Catchings, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855, 301-594-2041.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (the 1984 amendments) (Public Law 98-417), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a drug selected by the agency as the reference standard for bioequivalence testing. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA

are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug to which the ANDA refers.

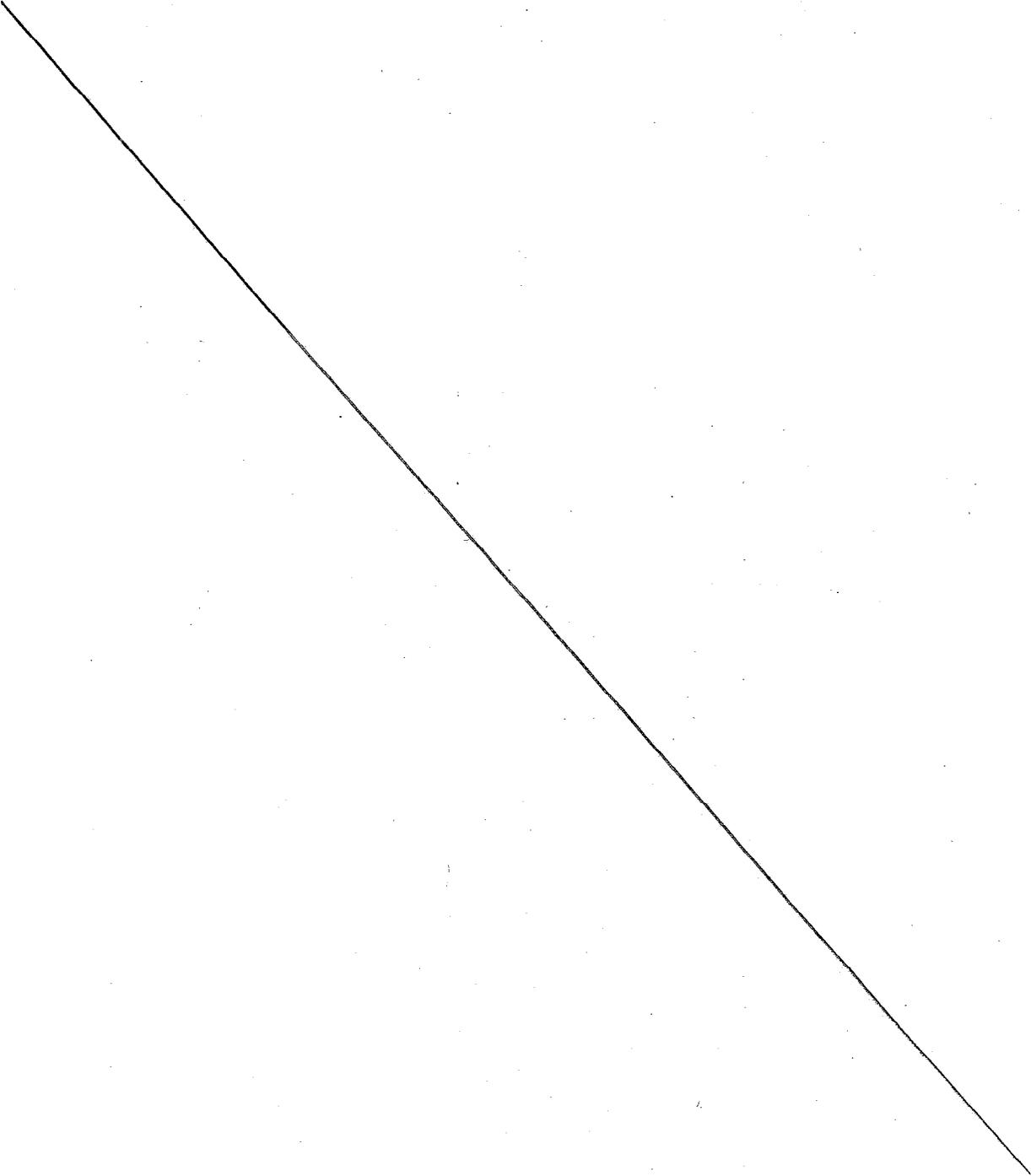
The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a)(2) (21 CFR 314.161(a)(2)), the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness if ANDAs that refer to the drug that was withdrawn are approved. Section 314.161(d) provides that if FDA determines that the listed drug was removed from sale for safety or effectiveness reasons, the agency will begin proceedings to withdraw approval of the ANDAs that refer to the drug that was withdrawn from sale.

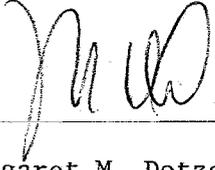
On May 4, 2001, Sidmak Laboratories, Inc. (Sidmak), submitted a citizen petition (Docket No. 01P-0245/CP1) under 21 CFR 10.25(a) and 10.30 to FDA. Sidmak requested that the agency determine whether disulfiram tablets were withdrawn from the market for reasons other than safety or effectiveness. Disulfiram 250- and 500-mg tablets are the subject of approved NDA 7-883, formerly held by Wyeth Ayerst under the tradename Antabuse. In its petition, Sidmak stated that it acquired all rights to NDA 7-883 from Wyeth Ayerst in December 2000 and that "concurrent with negotiations for this sale, Wyeth Ayerst discontinued the marketing of its disulfiram product."

FDA has reviewed its records and, under § 314.161, has determined that disulfiram 250- and 500-mg tablets approved under NDA 7-883 were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will maintain the listing for these products in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product

List" identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. The approval status of the approved ANDAs that refer to disulfiram 250- and 500-mg tablets is unaffected. Additional ANDAs for disulfiram 250- and 500-mg tablets may also be approved by the agency.



Dated: 9/18/01  
September 18, 2001.



Margaret M. Dotzel,  
Associate Commissioner for Policy.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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