

enforce certain sections of the FD&C Act in their own names, but provides that States must notify FDA before doing so. Section 100.2(d) (21 CFR 100.2(d)) sets forth the information that a State must provide to FDA in a letter of notification when it intends to take enforcement action under the FD&C Act against a particular food located in the State. The

information required under § 100.2(d) will enable FDA to identify the food against which the State intends to take action and advise the State whether Federal action has been taken against it. With certain narrow exceptions, Federal enforcement action precludes State action under the FD&C Act.

In the **Federal Register** of November 9, 2011 (76 FR 69742), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
100.2(d)	1	1	1	10	10

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated reporting burden for § 100.2(d) is minimal because enforcement notifications are seldom used by States. During the last 3 years, FDA has not received any new enforcement notifications; therefore, the Agency estimates that one or fewer notifications will be submitted annually. Although FDA has not received any new enforcement notifications in the last 3 years, it believes these information collection provisions should be extended to provide for the potential future need of a State government to submit enforcement notifications informing FDA when it intends to take enforcement action under the FD&C Act against a particular food located in the State.

Dated: February 23, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-P-0558]

Determination That PHENURONE (Phenacemide) Tablet, 500 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that PHENURONE (phenacemide) Tablet, 500 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to

approve abbreviated new drug applications (ANDAs) for phenacemide tablet, 500 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT:

Howard P. Muller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6234, Silver Spring, MD 20993-0002, 301-796-3602.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants 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 version of the drug that was previously approved. ANDA applicants 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.

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,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed 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).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

PHENURONE (phenacemide) Tablet, 500 mg, is the subject of NDA 007707, held by Abbott Laboratories, and initially approved on June 28, 1951. PHENURONE is an oral anticonvulsant indicated for the treatment of epilepsy.

In a letter dated May 14, 2003, Abbott Laboratories requested withdrawal of NDA 007707 for PHENURONE (phenacemide) Tablet. In the **Federal Register** of May 5, 2004 (69 FR 25124), FDA announced that it was withdrawing approval of NDA 007707, effective June 4, 2004.

Schiff & Company submitted a citizen petition dated October 16, 2008 (Docket No. FDA-2008-P-0558), under 21 CFR 10.30, requesting that the Agency determine whether PHENURONE (phenacemide) Tablet, 500 mg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records, FDA has determined under § 314.161 that PHENURONE (phenacemide) Tablet, 500 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that PHENURONE (phenacemide) tablet, 500 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of

PHENURONE (phenacemide) Tablet, 500 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list PHENURONE (phenacemide) Tablet, 500 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to PHENURONE (phenacemide) Tablet, 500 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: February 23, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-4783 Filed 2-28-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-1978-N-0441] (formerly 78N-0324); DESI 10392]

Drugs for Human Use; Drug Efficacy Study Implementation; Prescription Drugs That Contained Hydroxyzine Hydrochloride or Hydroxyzine Pamoate; Final Resolution of Docket

ACTION: Notice; withdrawal of a hearing request.

SUMMARY: The Food and Drug Administration (FDA) is announcing that all outstanding hearing requests pertaining to Docket FDA-1978-N-0441 (formerly 78N-0324) have been withdrawn. Therefore, shipment in interstate commerce of any of the products identified in that docket, or any identical, related, or similar (IRS) product that is not the subject of an approved new drug application (NDA) or abbreviated new drug application (ANDA) (other than an over-the-counter (OTC) product that complies with an applicable OTC monograph), is unlawful as of the effective date of this notice.

DATES: *Effective Date:* This notice is effective February 29, 2012.

ADDRESSES: All communications in response to this notice should be identified with the docket number found in brackets in the heading of this document, and directed to Pamela Lee, Office of Unapproved Drugs and Labeling Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5173, Silver Spring, MD 20993-0002.

FOR FURTHER INFORMATION CONTACT: Pamela Lee, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5173, Silver Spring, MD 20993-0002, 301-796-3297, email: pamela.lee@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

When initially enacted in 1938, the Federal Food, Drug, and Cosmetic Act (the FD&C Act) required that "new drugs" be approved for safety by FDA before they could legally be sold in interstate commerce.¹ To this end, the FD&C Act made it the sponsor's responsibility, before marketing a new drug, to submit an NDA to FDA to prove that its drug was safe. Between 1938 and 1962, if a drug obtained approval, FDA considered drugs that were IRS² to the approved drug to be "covered" by that approval, and allowed those IRS drugs to be marketed without independent approval.

In 1962, Congress amended the FD&C Act to require that new drugs be proven effective for their labeled indications, as well as safe, to obtain FDA approval. This amendment also caused FDA to conduct a retrospective evaluation of the effectiveness of the drug products that FDA had approved as safe between 1938 and 1962. FDA contracted with the National Academy of Sciences/National

Research Council (NAS/NRC) to make an initial evaluation of the effectiveness of over 3,400 products that had been approved only for safety between 1938 and 1962. The NAS/NRC reports for these drug products were submitted to FDA in the late 1960s and early 1970s. The Agency reviewed and re-evaluated the reports and published its findings in **Federal Register** notices. FDA's administrative implementation of the NAS/NRC reports was called the Drug Efficacy Study Implementation (DESI). DESI covered the approximately 3,400 products specifically reviewed by the NAS/NRC, as well as the even larger number of IRS products that entered the market without FDA approval.

All drugs covered by the DESI review are "new drugs" under the FD&C Act. If FDA's final DESI determination classifies a drug product as lacking substantial evidence of effectiveness for one or more indications, that drug product and those IRS to it may no longer be marketed for the indications and are subject to enforcement action as unapproved new drugs. If FDA's final DESI determination classifies the drug product as effective for one or more of its labeled indications, the drug can be marketed for those indications, provided it is the subject of an application approved for safety and effectiveness. Sponsors of drug products that have been found to be effective for one or more indications through the DESI process may rely on FDA's effectiveness determinations, but typically must update their labeling to conform to the indication(s) found to be effective by FDA and include any additional safety information required by FDA. Those drug products with NDAs approved before 1962 for safety therefore require approved supplements to their original applications if one or more indications are found to be effective under DESI; IRS drug products require an approved NDA or ANDA, as appropriate. Furthermore, labeling for drug products classified as effective may contain only those indications for which the review found the product effective, unless the firm marketing the product has received an approval for the additional indication(s).

II. Docket No. FDA-1978-N-0441 (formerly 78N-0324); DESI 10392

Under Docket No. FDA-1978-N-0441 (formerly 78N-0324), FDA evaluated the evidence of effectiveness for various indications for Atarax Tablets (NDA 10-392), Atarax Syrup (NDA 10-485), Vistaril Injection (NDA 11-111), Vistaril Capsules (NDA 11-459), and Vistaril Oral Suspension (NDA 11-795), products owned by Pfizer, Inc. (Pfizer),

¹ A "new drug" is defined by the FD&C Act as a drug that "is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a 'new drug' if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use * * *." (21 U.S.C. 321(p)).

² Section 310.6(b)(1) ((21 CFR 310.6(b)(1)) provides: "An identical, related, or similar drug includes other brands, potencies, dosage forms, salts, and esters of the same drug moiety as well as of any drug moiety related in chemical structure or known pharmacological properties."