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 We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.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]

BILLING CODE 4160–01–P

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is announcing that all outstanding hearing requests pertaining to Docket FDA–1978–N–0441 (formerly 78N–0324) have been withdrawn.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 IRS [2] 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.''

and B. Roerig & Co., then a division of Pfizer, that contained hydroxyzine hydrochloride and hydroxyzine pamoate (44 FR 6780, February 2, 1979) (the February 1979 **Federal Register** notice). Although some indications for these products were found to be supported by adequate and well-controlled clinical studies, other indications were determined to be lacking substantial evidence of effectiveness (Id.). The February 1979 **Federal Register** notice offered an opportunity for hearing with respect to the indications found to be lacking substantial evidence of effectiveness, as well as with respect to any issues relating to the legal status of the drug products subject to it.

In response to the February 1979 **Federal Register** notice, Pfizer requested a hearing. No other companies requested a hearing. On November 22, 2010, FDA sent a letter to Pfizer to determine whether Pfizer remained interested in pursuing its hearing request. On December 22, 2010, Pfizer responded by withdrawing its hearing request. There are no longer outstanding hearing requests pertaining to Docket No. FDA–1978–N–0441 (formerly 78N–0324). Therefore, shipment in interstate commerce of any product identified in this docket, or any IRS product, that is not the subject of an approved NDA or ANDA is unlawful as of the effective date of this notice. This notice is not applicable to OTC products that comply with an OTC monograph (21 CFR 310.6(f)). Any person who wishes to determine whether a specific product is covered by this notice should write to the Center for Drug Evaluation and Research (see ADDRESSES).

III. Discontinued Products

Some firms may have previously discontinued the manufacturing or distribution of products covered by this notice without removing them from the listing of their products under section 510(j) of the FD&C Act (21 U.S.C. 360(j)). Other firms may discontinue manufacturing or marketing listed products in response to this notice. Firms that wish to notify the Agency of product discontinuation should send a letter, signed by the firm's chief executive officer, fully identifying the discontinued product(s), including National Drug Code (NDC) number(s), and stating that the product(s) have been discontinued. The letter should be sent to Pamela Lee (see **ADDRESSES**).

Firms should also update the listing of their products under section 510(j) of the FD&C Act to reflect discontinuation of unapproved products. FDA plans to rely on its existing records, including drug listing records or other available information, when it targets violations for enforcement action. Firms should be aware that after the effective date of this notice, FDA intends to take enforcement action without further notice against any firm that manufactures or ships in interstate commerce any unapproved product covered by this notice.

IV. Reformulated Products

FDA cautions firms against reformulating products into OTC products or different unapproved new drugs that are marketed under the same name or substantially the same name (including a new name that contains the old name). Reformulated products marketed under a name previously identified with a different active ingredient or combination of active ingredients have the potential to confuse health care practitioners and harm patients.

This notice is issued under the FD&C Act (sections 502 and 505 (21 U.S.C. 352 and 355)), and under authority delegated to the Deputy Commissioner for Policy under section 1410.10 of the FDA Staff Manual Guide.

Dated: February 17, 2012.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2012–4781 Filed 2–28–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0024]

Guidance for Industry on Size of Beads in Drug Products Labeled for Sprinkle; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Size of Beads in Drug Products Labeled for Sprinkle.'' This guidance provides applicants preparing or submitting new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics licensing applications (BLAs) the Center for Drug Evaluation and Research's (CDER's) current thinking on appropriate size ranges for beads in drug products that are labeled to be administered via sprinkling (e.g., capsules or packets containing beads).

In the **Federal Register** of January 19, 2011 (76 FR 3144), FDA announced the availability of the draft version of this guidance. The public comment period closed on April 19, 2011. A number of comments were received from the public, all of which the Agency considered carefully as it finalized the guidance and made appropriate changes.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Laurie Muldowney, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 51, rm. 4154, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1571.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Size of Beads in Drug Products Labeled for Sprinkle.'' This guidance provides applicants preparing or submitting NDAs, ANDAs, and BLAs CDER's current thinking on appropriate size ranges for beads in drug products that are labeled to be administered via sprinkling (e.g., capsules or packets containing beads).

Certain drug products that contain beads within a capsule indicate in the labeling that the capsule can be broken and the internal beads can be sprinkled on soft foods and swallowed without chewing as an alternative administration technique. This is particularly common with drug products designed to have extended- or delayed-release characteristics (i.e., the beads are manufactured to release the drug product at different rates). To make certain that the intended product performance is achieved—whether from a capsule that has been broken or from