

ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

ALBAMYCIN (novobiocin sodium) capsule, 250 mg, is the subject of NDA 50-339, held by Pfizer, Inc. (Pfizer), and initially approved on September 4, 1964. ALBAMYCIN is indicated for the treatment of serious infections due to susceptible strains of *Staphylococcus aureus* when other less toxic antibiotics such as the penicillins, cephalosporins, vancomycin, lincomycin, erythromycin, and the tetracyclines cannot be used.

Novobiocin antibiotic drug products were reviewed for efficacy under the Drug Efficacy Study Implementation (DESI) program. Under this program, implemented in response to the 1962 amendments to the FD&C Act requiring demonstration of effectiveness (The Kefauver-Harris Amendments, Public Law 87-781 (1962)), the National Academy of Sciences-National Research Council (NAS-NRC) undertook a study of some 4,000 drug formulations to assess the efficacy of the products. Upon consideration of the findings and recommendations of the NAS-NRC, FDA set forth in the **Federal Register** its conclusions and assessment of whether and under what circumstances the reviewed drug products are considered "effective" for use as required by the FD&C Act.

In the **Federal Register** of May 2, 1969 (34 FR 7252), FDA announced its conclusions following consideration of the findings and recommendations of the NAS-NRC regarding oral and parenteral forms of novobiocin including ALBAMYCIN (novobiocin sodium) capsule, 250 mg. The announcement stated that FDA had concluded that novobiocin is effective for certain indications and provided labeling guidelines in accordance with this conclusion. We note, however, that the initial panel review of a syrup form of novobiocin raised questions, even at that time, concerning the safety and effectiveness of this antibiotic. The panel report included the following statement: "The development of safer and more effective drugs has virtually eliminated the need for novobiocin. The majority of the Panel believes that orally administered novobiocin should be taken off the market." Report of the

Anti-Infectives Panel, National Academy of Sciences-National Research Council, Albamycin Syrup.

In an annual report received on June 9, 1999, Pharmacia & Upjohn (now Pfizer, Inc.) notified FDA that ALBAMYCIN (novobiocin sodium) capsule, 250 mg, was no longer being manufactured. In a letter dated June 27, 2007, Pfizer, then the current holder of NDA 50-339, notified FDA that ALBAMYCIN (novobiocin sodium) capsule, 250 mg, had been discontinued. In the **Federal Register** of February 11, 2009 (74 FR 6896), FDA announced that it was withdrawing approval of NDA 50-339 in response to Pfizer's withdrawal request. As a result, ALBAMYCIN (novobiocin sodium) capsule, 250 mg, was moved to the "Discontinued Drug Product List" section of the Orange Book.

Crixmore LLC submitted a citizen petition dated July 9, 2008 (Docket No. FDA-2008-P-0431), under 21 CFR 10.30, requesting that the Agency determine whether ALBAMYCIN (novobiocin sodium) capsule, 250 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 ALBAMYCIN (novobiocin sodium) capsule, 250 mg, was withdrawn for reasons of safety or effectiveness. The petitioner stated that it had identified no data or other information suggesting that ALBAMYCIN (novobiocin sodium) capsule, 250 mg, was withdrawn for reasons of safety or effectiveness and speculated that the discontinuation of this product was an economic/strategic decision totally unrelated to safety and/or efficacy. We have carefully reviewed our files for records concerning the withdrawal of ALBAMYCIN (novobiocin sodium) capsule, 250 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. The literature and adverse event reports reveal several significant safety concerns. Reported adverse reactions include relatively common skin reactions, jaundice, hepatic failure, and blood dyscrasias (neutropenia, anemia, and thrombocytopenia). The literature also reveals concern about the development of novobiocin-resistant *Staphylococci* during treatment, and a potential for drug interactions. In light of the significant safety concerns with this product, we conclude that the withdrawal of this product from the market was on the basis of safety or effectiveness.

Accordingly, the Agency will remove ALBAMYCIN (novobiocin sodium)

capsule, 250 mg, from the list of drug products published in the Orange Book. FDA will not accept or approve ANDAs that refer to this drug product.

Dated: January 13, 2011.

**David Dorsey,**

*Acting Deputy Commissioner for Policy, Planning and Budget.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA-2011-D-0024]

#### **Draft 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 draft guidance for industry entitled "Size of Beads in Drug Products Labeled for Sprinkle." This draft guidance provides sponsors of 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).

**DATES:** Although you can comment on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 19, 2011.

**ADDRESSES:** Submit written requests for single copies of the draft 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 draft guidance document.

Submit electronic comments on the draft 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 (HFD-003), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4154, Silver Spring, MD 20993-0002, 301-796-1571.

**SUPPLEMENTARY INFORMATION:****I. Background**

FDA is announcing the availability of a draft guidance for industry entitled "Size of Beads in Drug Products Labeled for Sprinkle." This draft guidance provides sponsors of 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 on 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—be it from a capsule that has been broken or from a packet containing beads—it is important to have reasonable assurance that the patient will be able to swallow the beads with the food that the beads are mixed with without stimulating the urge to chew. Additional assurances may be needed when the label also includes language for alternate administration via an enteral feeding tube.

The recommendations in this draft guidance are based on literature on chewing and swallowed particle size and on Agency experience with NDAs and ANDAs submitted for these dosage forms. Three parameters are considered in this draft guidance as they relate to drug products labeled for sprinkle: (1) Appropriate maximum size for the beads, (2) special considerations for sprinkle drug products that include language for alternate administration via an enteral feeding tube, and (3) how to address potential bead size differences between reference listed drugs and ANDAs and meet bioavailability (BA) or bioequivalence (BE) recommendations.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on size of beads in drug products labeled for sprinkle. It does not create or confer any rights for or on any person

and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

**II. Comments**

Interested persons may submit to the Division of Dockets Management (*see ADDRESSES*) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**III. The Paperwork Reduction Act of 1995**

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). Information submitted in an NDA, ANDA, or BLA supporting the appropriate size for beads in drug products that are labeled to be administered via sprinkling, including related BA and BE studies, is approved by OMB under control number 0910-0001 for NDAs and ANDAs and control number 0910-0338 for BLAs.

**IV. Electronic Access**

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: January 12, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-1001 Filed 1-18-11; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2010-N-0611]

**Pediatric Device Consortia Grant Program (P50)**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of the Office of Orphan Products Development (OOPD) Pediatric Device Consortia Grant Program. The goal of the Pediatric Device Consortia Grant Program is to promote pediatric device development by providing grants to nonprofit consortia whose business model and approach to device development will either result in, or substantially contribute to, market approval of medical devices designed specifically for use in children. The program does not support the development of single device projects. Although administered by the Office of Orphan Products Development, this grant program is intended to encompass devices that could be used in all pediatric conditions or diseases, not just rare diseases. The pediatric population (neonates, infants, children, and adolescents) includes patients who are 21 years of age or younger at the time of diagnosis or treatment.

**DATES:** Important dates are as follows:

1. The application due date is May 2, 2011.
2. The anticipated start date is September, 2011.
3. The opening date is January 15, 2011.
4. The expiration date is May 3, 2011.

**For Further Information and Additional Requirements Contact:**

Linda C. Ulrich or Debra Y. Lewis, Office of Orphan Products Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 32, rm. 5271, Silver Spring, MD 20993-0002, 301-796-8660 or Camille Peake, Office of Acquisitions & Grant Services, Food and Drug Administration, 5630 Fishers Lane, rm. 2139, Rockville, MD 20852, 301-827-7175.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA when posted and located at: <http://grants.nih.gov/grants/guide/index.html>.

**SUPPLEMENTARY INFORMATION:****I. Funding Opportunity Description**

RFA-FD-011-002.  
*Catalog of Federal Domestic Assistance Number:* 93.103.

**A. Background**

The development of pediatric medical devices currently lags 5 to 10 years behind the development of devices for adults. Children differ from adults in terms of their size, growth, development, and body chemistry,