DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Child Care; Delegation of Authority

Notice is hereby given that I have delegated to the Director, Office of Child Care, Administration for Children and Families, the authorities vested in me by the Secretary of Health and Human Services in the memorandum dated August 20, 1991, pertaining to the Head Start Program and the Child Development Associate Scholarship Assistance Grants Program; in the memorandum dated August 20, 1991, pertaining to the Omnibus Budget Reconciliation Act of 1981; in the memorandum dated August 20, 1991, pertaining to the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990, Pub. L. 101–508); and in the memorandum dated September 16, 1997, pertaining to the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA, Pub. L. 104–193), as amended, as they pertain to the functions assigned to the Office of Child Care.

(a) Authorities Delegated

1. Authority to administer the provisions of the Child Development Associate Scholarship Assistance Act, 42 U.S.C. 10901–10905, and as amended now and hereafter.

2. Authority to administer the provisions of Subchapter D—Grants for Planning and Development of Dependent Care Programs and for other purposes (Chapter 8, Title VI of the Omnibus Budget Reconciliation Act of 1981, Pub. L. 97–35, 42 U.S.C. 9871 *et seq.*) and as amended now and hereafter.

3. Authority for the Child Care and Development Block Grants, under Section 5082 of OBRA 1990, (42 U.S.C. 9858 *et seq.*), and as amended now and hereafter.

4. Authority to administer the provisions of the Child Care and Development Block Grant Amendments of 1996, 42 U.S.C. 9801 note, under Sections 601–615 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, 42 U.S.C. 1305 note, 42 U.S.C. 601 *et seq.,* and as amended now and hereafter.

(b) Limitations

1. These authorities shall be exercised under the Department's policy on regulations and the existing delegation of authority to approve and issue regulations.

2. This delegation does not include the authority to submit reports to Congress and shall be exercised under financial and administrative requirements applicable to all Administration for Children and Families authorities.

3. The approval or disapproval of grant applications and the making of grant awards require concurrence of the appropriate Grants Officer. The approval or disapproval of contract proposals and awards are subject to the requirements of the Federal Acquisition Regulations and requires the concurrence of the Contracting Officer.

4. This delegation of authority does not include the authority to sign and issue notices of grant awards.

5. This delegation of authority does not include the authority to appoint Action Officials for Audit Resolution.

6. This delegation of authority does not include the authority to appoint Central Office or Regional Office Grant Officers for the administration of the child care related programs.

7. This delegation of authority does not include the authority to hold hearings.

8. This delegation of authority does not include the authority to approve or disapprove awards for grants or contracts for research, demonstration, or evaluations relating to child care.

9. Any re-delegation shall be in writing and prompt notification must be provided to all affected managers, supervisors, and other personnel, and requires the concurrence of the Deputy Assistant Secretary for Administration.

(c) Effect on Existing Delegations

This delegation supersedes all existing delegations of these authorities.

(d) Effective Date

This delegation is effective immediately. I hereby affirm and ratify any actions taken by the Director, Office of Child Care, or his or her subordinates, which involved the exercise of the authorities delegated herein prior to the effective date of this delegation.

Dated: January 10, 2011.

David A. Hansell,

Acting Assistant Secretary for Children and Families.

[FR Doc. 2011–1067 Filed 1–18–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–P–0431]

Determination That ALBAMYCIN (Novobiocin Sodium) Capsule, 250 Milligrams, Was 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 ALBAMYCIN (novobiocin sodium) capsule, 250 milligrams (mg) was withdrawn from sale for reasons of safety or effectiveness. The Agency will not accept or approve abbreviated new drug applications (ANDAs) for ALBAMYCIN (novobiocin sodium) capsule, 250 mg.

FOR FURTHER INFORMATION CONTACT: Nancy Hayes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6244, Silver Spring, MD 20993–0002, 301–796–3601.

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 (FD&C 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). 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.

[FR Doc. 2011–1000 Filed 1–18–11; 8:45 am]

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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.