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.

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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