

**FOR FURTHER INFORMATION CONTACT:** Margaret F. Sharkey, Center for Drug Evaluation and Research (HFD-366), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-3041.

**SUPPLEMENTARY INFORMATION:** In a notice published in the *Federal Register* of April 15, 1988 (53 FR 12862), the Director of the Center for Drug Evaluation and Research offered an opportunity for a hearing on a proposal to withdraw approval of antibiotic applications and abbreviated antibiotic applications for nonsterile neomycin sulfate for prescription compounding not labeled in accordance with applicable amended antibiotic regulations (21 CFR 444.942a). In the same issue (53 FR 12644), FDA amended the regulations governing these products and offered a labeling guideline because the drug was being used for indications for which it lacked evidence of safety and effectiveness, and for which there was clinical evidence of significant risk to the patient. The final rule became effective on June 14, 1988.

The amendments to 21 CFR 444.942a changed the product name from "neomycin sulfate for prescription compounding" to "neomycin sulfate for compounding oral products" and required product labeling to provide information concerning appropriate uses and to warn about the risks associated with inappropriate use.

Manufacturers and suppliers were notified that they would have to supplement their applications within 60 days of the effective date of the final rule to provide for the new product name and package insert labeling. Alternatively, a manufacturer or supplier could request a hearing. No supplements were submitted for any of the applications. One supplier, Pharma-Tek, Inc., requested a hearing.

The sponsors of the five products listed below failed to file a request for a hearing and did not supplement their applications. Accordingly, FDA is withdrawing approval of the following AADA's:

1. AADA 61-043; held by The Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001.
2. AADA 61-305; held by Pfizer, Inc., 235 East 42nd St., New York, NY 10017.
3. AADA 61-169; held by S.B. Penick and Co., 540 New York Ave., Lyndhurst, NJ 07071.
4. AADA 61-698; held by Elkins-Sinn, Inc., 2 Esterbrook Lane, Cherry Hill, NJ 08034.
5. AADA 62-385; held by Paddock Laboratories, Inc., 3101 Louisiana Ave. North, Minneapolis, MN 55421.

The Director of the Center for Drug Evaluation and Research, under the Federal Food, Drug, and Cosmetic Act (sec. 505(e), 52 Stat. 1052-1053 as amended (21 U.S.C. 355(e))) and under authority delegated to him (21 CFR 5.82), finds that clinical or other experience, tests, or other scientific data show that the drug products listed above are unsafe for use under the conditions of use upon basis for which their applications were approved. Therefore, pursuant to the foregoing finding, approval of the AADA's listed above is hereby withdrawn effective January 5, 1989. Shipment in interstate commerce of the products listed above will then be unlawful.

This notice does not apply to AADA 61-579, held by Pharma-Tek, Inc., P.O. Box AB, Huntington, NY 11743. The product covered by AADA 61-579 is the subject to a pending hearing request and will be the subject of a future *Federal Register* announcement.

Dated: November 23, 1988.

Carl C. Peck,

Director, Center for Drug Evaluation and Research.

[FR Doc. 88-28027 Filed 12-5-88; 8:45 am]  
BILLING CODE 4160-01-0

[Docket No. 79N-0151]

**Oligosaccharide Antibiotic Drugs;  
Neomycin Sulfate for Injection;  
Withdrawal of Approval of  
Abbreviated Antibiotic Drug  
Applications**

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing approval of four abbreviated antibiotic drug applications (AADA's) for neomycin sulfate in sterile vials for injection. This withdrawal action is being taken because the risks involved in the parenteral use of neomycin sulfate are judged to outweigh any benefits that may be derived from its continued availability.

**EFFECTIVE DATE:** January 5, 1989.

**FOR FURTHER INFORMATION CONTACT:** Margaret F. Sharkey, Center for Drug Evaluation and Research (HFD-366), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-3041.

**SUPPLEMENTARY INFORMATION:** In a notice published in the *Federal Register* of April 15, 1988 (53 FR 12864), the Director of the Center for Drug Evaluation and Research offered an

opportunity for a hearing on a proposal to withdraw approval of antibiotic applications and abbreviated antibiotic applications for neomycin sulfate in sterile vials for parenteral use. FDA also amended the antibiotic regulations for sterile neomycin sulfate (21 CFR 444.42a) by deleting all provisions for the injectable dosage form so that neomycin sulfate packaged in sterile vials for dispensing could not be certified or released (see 53 FR 12658; April 15, 1988). These actions were deemed necessary because of the toxicity associated with the unapproved use of this drug in the irrigation of wounds. In addition, the Director concluded that the use of this dosage form for the single remaining approved indication, the treatment of urinary tract infection, is no longer acceptable because of the availability of newer, safer antibiotics that are as effective as, or more effective than, parenteral neomycin sulfate and that do not present comparable risks.

In response to the April 15, 1988, *Federal Register* notice, no holders of approved applications requested a hearing. Accordingly, FDA is withdrawing approval of the following applications:

1. AADA 60-366, Neomycin Sulfate for Injection, U.S.P., held by E. R. Squibb & Sons, Inc., P.O. Box 4000, Princeton, NJ 08540.
2. AADA 60-477, Mycifradin Injectable, held by The Upjohn Co., Kalamazoo, MI 49001.
3. AADA 61-084, Neomycin Sulfate for Injection, held by Pfizer Inc., 235 East 42nd St., New York, NY 10017.
4. AADA 61-198, Neomycin Sulfate for Injection, U.S.P., held by Elkins-Sinn, Inc., 2 Esterbrook Lane, Cherry Hill, NJ 08034.

The Director of the Center for Drug Evaluation and Research, under the Federal Food, Drug and Cosmetic Act (sec. 505(e), 52 Stat. 1052-1053 as amended (21 U.S.C. 355(e))) and under authority delegated to him (21 CFR 5.82), finds that clinical or other experience, tests, or other scientific data show that the drug products listed above are unsafe for use under the conditions of use upon the basis for which their applications were approved. Therefore, pursuant to the foregoing finding, approval of the AADA's listed above is hereby withdrawn effective January 5, 1989. Shipment in the interstate commerce of the products listed above will then be unlawful.

Dated: November 23, 1988.

Carl C. Peck,

Director, Center for Drug Evaluation and Research.

(FR Doc. 38-28023 Filed 12-5-88; 3:45 am)

BILLING CODE 4180-01-01

**Health Care Financing Administration**  
(OACT-22-N)

**Medicare Program; Employers and Duplicative Medicare Benefits**

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the national average actuarial value of additional Medicare Part A benefits available in 1989 as a result of the Medicare Catastrophic Coverage Act of 1988. Employers are required to examine the extent to which health benefits they provide to employees and retired former employees entitled to Medicare (including coverage for employees' and retired former employees' dependents entitled to Medicare) duplicate the new Part A and Part B benefits. If the duplicative benefits have a national average actuarial value of at least 50 percent of the value of the new Medicare benefits, the employer must offer a refund, additional benefits, or some combination thereof.

In computing the actuarial values of the duplicative benefits, employers have the option of using national average actuarial values we establish or calculating the actuarial value based on guidelines we establish. This notice contains both the national actuarial values we have determined and the guidelines for employers to use.

**EFFECTIVE DATES:** The provisions of this notice concerning Part A are effective January 1, 1989. The provisions of this notice concerning Part B are effective January 1, 1990.

**FOR FURTHER INFORMATION CONTACT:** Kenneth Leong, (301) 966-7908, concerning the actuarial values and guidelines.

Herbert Pollock, (301) 966-4474, concerning all else.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The Medicare Catastrophic Coverage Act of 1988 (Pub. L. 100-360) was enacted on July 1, 1988. This act, which provides for benefits not previously available under Medicare, protects beneficiaries against costs associated with a catastrophic illness. The Act provides for expanded Part A benefits

effective January 1, 1989 and expanded Part B benefits effective January 1, 1990.

Many beneficiaries have private health insurance coverage that supplements Medicare, usually through health benefits plans of current or past employers. Some of these health benefits plans offer protection against the costs of a catastrophic illness by limiting beneficiary out-of-pocket expenses or offering additional benefits, such as a longer period of hospitalization than Medicare covered; some plans may do both. In addition, some plans pay deductibles, coinsurances, the Part A premium where applicable, the Part B premium, or some combination of these benefits.

With the availability of expanded Medicare coverage beginning in 1989, beneficiaries that now are receiving additional benefits through their employers' health benefits plans would find that the coverages are duplicative and they reap little, if any, benefit from the Medicare catastrophic coverage changes. Therefore, Congress included section 421 in Pub. L. 100-360, which ensures that if an employer provided to employees or retired former employees, as of July 1, 1988 (the date of enactment of Pub. L. 100-360) benefits that will be available to Medicare beneficiaries as a result of Pub. L. 100-360, the employer must offer additional benefits, a refund, or a combination thereof, if the duplicative benefits have an actuarial value of at least 50 percent of the national average actuarial value of the benefits added or increased by Pub. L. 100-360. Congress enacted technical amendments to section 421 in section 608(A) of The Family Support Act of 1988 (Pub. L. 100-485 October 13, 1988).

More specifically, under section 421 the employer must (1) provide additional benefits to the employee or retired former employee that are at least equal in actuarial value to the duplicative benefits, (2) refund to the employee or retired former employee an amount of money equal in actuarial value to the duplicative benefits, or (3) provide a combination of additional benefits and refunds that total at least the actuarial value of the duplicative benefits. In computing the actuarial value of the duplicative Part A benefits (beginning January 1989) and duplicative Part B benefits (beginning January 1990), employers have the option of using national average actuarial values published by the Secretary or calculating the actuarial value based on guidelines published by the Secretary.

<sup>1</sup> Note.—To avoid repetition, the term "employee", when used in this notice, also includes retired former employees.

**II. Provisions of This Notice**

This notice provides the actuarial values for the benefits added by Pub. L. 100-360; specifies the employers to whom the notice applies; defines "additional benefits"; gives the applicable effective dates; defines duplicative benefits; contains the guidelines for employers to use to compute the actuarial value of duplicative benefits; and lists some of the benefits added by Pub. L. 100-360.

**A. National Average Actuarial Value of the Medicare Benefits Added or Increased by Pub. L. 100-360**

The national average actuarial value of the Medicare Part A benefits added or increased by Pub. L. 100-360 was \$61 as of July 1, 1988. This is the cost of providing the increased Part A benefits for each beneficiary enrolled. Fifty percent of this amount is \$30.50 per year. For 1989, the national average actuarial value is \$65. The national average actuarial value of the Part B benefits added or increased by Pub. L. 100-360 will be published prior to January 1, 1990.

**B. Responsibility of Employers**

Employers are responsible for determining if, as of July 1, 1988, they offered to their employees or retired former employees who are covered by Medicare any duplicative Part A benefits (as defined in D. below) and, if so, the actuarial value of any such benefits on July 1, 1988. If the actuarial value of their duplicative Part A benefits was, as of July 1, 1988, 50 percent of the 1989 national average actuarial value of the Medicare benefits added or increased under Pub. L. 100-360 (discounted to the value as of July 1, 1988), the employer is required to offer additional benefits or refunds, or a combination of additional benefits and refunds, equal in actuarial value to the value of the duplicative benefits determined as if they were provided in 1989.

If an employer provides only additional benefits, the benefits must be equal in value at least to the 1989 national average actuarial value of the duplicative Part A benefits that were provided by the employer to employees as of July 1, 1988. Employers may provide a wide range of additional benefits as long as they are equal in value to at least the actuarial value of the duplicative benefits. The additional benefits may consist of health care benefits that do not duplicate the new Medicare benefits and may include payment of the Part B premium, provided the employer was not already