

the State's mental retardation/developmental disabilities service system and the degree of quality assurance reform toward an outcome-focused system."

"Reinventing Quality—The 1998 Sourcebook of Innovative Programs for the Quality Assurance and Quality Improvement of Community Services", Institute on Community Integration/University of Minnesota, reaffirms this trend in the States as reported by HSRI and reasserts the need to change the service standards to reflect the evolution to community-based, individual needs. In the background section of this book, it states "Recent years have seen a shift in long-term care for persons with developmental disabilities from large institutions to community settings. But people receiving community services can fully realize the potential for improved quality of life afforded by this movement only if quality assurance expectations and activities are changed significantly from those originally developed for institutional care." Efforts to improve the quality of community services have demonstrated many innovative and comprehensive quality assessment and enhancement practices that are contained in the Sourcebook. It is these efforts that "may help others to fashion their own responses that not only protect the basic safety and well-being of individuals, but also encourage and support their preferred choices, personal growth, and individual lifestyles." One set of efforts described is consumer and family monitoring initiatives. Eight programs are profiled outlining their attempts at gaining insight into the quality of life of residents at group homes and other smaller facilities and providing feedback for quality enhancement.

It is obvious that "monitoring" in the traditional sense of the word is no longer an acceptable method for determining the quality of services and supports to people with developmental disabilities and their families. Thus, ADD is very interested in supporting models that demonstrate the effectiveness and cost efficiency of using volunteer surveyors of community residencies to gather objective information on the quality of life or outcomes experienced by their residents. The purpose of these projects would be to assist in the development of quality assurance improvements in their states. Projects should consider how their activities could contribute to an integrated service system based on person-centered outcomes. Any tools or instruments of measurement used should have as their focus the needs of the individual. These tools or

instruments should be tested for reliability or validity and be standardized. Also, any tools/instruments should offer interpretive guidelines for those expected to use them. These projects would be expected to include in their community surveying multiple community settings (rural and urban), different types of housing (group homes, supported living, ownership) and all ranges of disability from mild to severe, especially those with limited communication skills. Projects should address cultural and geographic issues in their surveying as well. Consideration should be given to any issues regarding liability and insurance that may effect the implementation of the project. Models that ADD would seriously consider for funding should incorporate recruitment of consumers and family members and advocates, training of prospective surveyors, and direct observation and contact of residents.

(Federal Catalog of Domestic Assistance Number 93.631—Developmental Disabilities—Projects of National Significance)

Dated: April 14, 1999.

**Sue Swenson,**

*Commissioner, Administration on Developmental Disabilities.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Head Start Bureau; Advisory Committee on Head Start Research and Evaluation; Notice of Meeting; Correction

**AGENCY:** Administration on Children, Youth and Families, ACF, DHHS.

**ACTION:** Correction.

**SUMMARY:** On Monday, April 5, 1999, a Notice was published in the **Federal Register**, document 99-8316, page 16470 announcing the Advisory Committee on Head Start Research and Evaluation meeting to be held on April 26-27, 1999 at Georgetown University. The Head Start Web site was incorrectly cited as <http://www.dhhs.gov/programs/hsb>. The correct web site is <http://www2.acf.dhhs.gov/programs/hsb>. For further information contact Deborah Roderick Stark at 301/889-0430.

Dated: April 12, 1999.

**Patricia Montoya,**

*Commissioner, Administration on Children, Youth, and Families.*

[FR Doc. 99-9861 Filed 4-19-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 77N-0240; DESI 1786]

#### Certain Single-Entity Coronary Vasodilators Containing Controlled-Release Nitroglycerin; Opportunity for a Hearing

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to withdraw approval of 23 new drug applications (NDA's) and abbreviated new drug applications (ANDA's) for certain single-entity coronary vasodilator drug products containing controlled-release nitroglycerin. FDA is offering the holders of the applications an opportunity for a hearing on the proposal. The basis for the proposal is that the sponsors of these products have failed to submit acceptable data on bioavailability and bioequivalence.

**DATES:** Hearing requests are due by May 20, 1999; data and information in support of hearing requests are due by June 21, 1999.

**ADDRESSES:** Communications in response to this notice should be identified with the reference number DESI 1786, and directed to the attention of the appropriate office named as follows:

A request for a hearing, supporting data, and other comments are to be identified with Docket No. 77N-0240 and submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

A request for applicability of this notice to a specific product should be directed to the Division of Prescription Drug Compliance and Surveillance (HFD-330), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

#### FOR FURTHER INFORMATION CONTACT:

Mary E. Catchings, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers

Lane, Rockville, MD 20857, 301-594-2041.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In a notice (DESI 1786) published in the **Federal Register** of February 25, 1972 (37 FR 4001), FDA announced its evaluation of reports received from the National Academy of Sciences/National Research Council, Drug Efficacy Study group, on certain coronary vasodilator drugs. FDA classified controlled-release tablets of nitroglycerin as possibly effective for indications relating to the management, prophylaxis, or treatment of anginal attacks.

Notices published in the **Federal Register** of August 26, 1977 (42 FR 43127), October 21, 1977 (42 FR 56156), and September 15, 1978 (43 FR 41282), amended earlier notices (37 FR 26623, December 14, 1972; and 38 FR 18477, July 11, 1973) by temporarily exempting nitroglycerin in controlled-release forms from the time limits established for the Drug Efficacy Study Implementation (DESI) program. The notices established conditions for marketing these products and identical, similar, or related products § 310.6 (21 CFR 310.6), whether or not they had been marketed and whether or not they were subjects of approved NDA's. FDA required distributors and manufacturers to have ANDA's (conditionally approved, pending the results of ongoing studies) to market controlled-release nitroglycerin products not the subject of NDA's. If at least one drug sponsor was conducting clinical studies on a chemical entity, FDA permitted the marketing of all firms' products containing the same chemical entity in a similar dosage form, provided each product met the other conditions established in the notices. Not all sponsors, therefore, were required to conduct clinical studies. Because bioavailability is specific for an individual product, however, FDA required each firm to conduct a bioavailability study on its own product.

In a notice published in the **Federal Register** of September 7, 1984 (49 FR 35428), after completing its review of the clinical studies submitted for single-entity controlled-release nitroglycerin capsules and tablets, FDA announced that it had concluded that these drugs are effective for prevention for angina pectoris. The notice set forth the marketing and labeling conditions for the products. It required sponsors of these products seeking full approval to submit supplements providing acceptable in vitro dissolution tests and in vivo bioavailability/bioequivalence

studies. The September 1984 notice stated that applications not fully approved within 1 year would be subject to proceedings to withdraw the previous approval and to remove the products from the market. This deadline was extended to June 26, 1987, in a notice published in the **Federal Register** of December 26, 1985 (50 FR 52856).

The sponsors of the drug products listed in section II of this document are not in compliance with the notices of September 7, 1984, and December 26, 1985, in that they either have not submitted any bioavailability/bioequivalence data or have not submitted additional data on incomplete or inadequate studies. Accordingly, this notice reclassifies these products as lacking substantial evidence of effectiveness, proposes to withdraw approval of their applications, and offers an opportunity for a hearing on the proposal.

##### II. NDA's and ANDA's Known by FDA to be Subject to This Notice

- NDA 16-447; Nitrospan (controlled-release) Capsules containing 2.5 milligrams (mg) nitroglycerin per capsule; Rhone-Poulenc Rorer Pharmaceutical, Inc. (formerly held by USV Laboratories), 500 Arcola Rd., Collegeville, PA 19426-0107.

- NDA 16-518; Nitro-Bid (controlled-release) Capsules containing 2.5 mg nitroglycerin per capsule; Hoechst Marion Roussel (formerly held by Marion Laboratories, Inc.), 10236 Marion Park Dr., Kansas City, MO 64137.

- NDA 16-975; Nitro-Bid (controlled-release) Capsules containing 6.5 mg nitroglycerin per capsule; Hoechst Marion Roussel.

- NDA 17-384; Nitrong (controlled-release) Tablets containing 2.6 mg nitroglycerin per tablet; Wharton Laboratories, Inc., Division of U.S. Ethicals, Inc., 37-02 48th Ave., Long Island City, NY 11101.

- ANDA 86-126; Nitrong (controlled-release) Tablets containing 6.5 mg nitroglycerin per tablet; Wharton Laboratories.

- ANDA 86-138; Nitrong (controlled-release) Tablets containing 2.6 mg nitroglycerin per tablet; Wharton Laboratories.

- ANDA 86-214; Nitrospan (controlled-release) Capsules containing 2.5 mg nitroglycerin per capsule; Rhone-Poulenc Rorer.

- ANDA 86-426; Nitro-Bid (controlled-release) Capsules containing 13 mg nitroglycerin per capsule; Hoechst Marion Roussel.

- ANDA 86-537; Nitroglycerin Controlled-Release Capsules containing

- 6.5 mg of the drug per capsule; KV Pharmaceutical Co., 2503 South Hanley Rd., St. Louis, MO 63144-2555.

- ANDA 86-787; Sustac (controlled-release) Tablets containing 10 mg nitroglycerin per tablet; Forest Laboratories, 909 Third Ave., New York, NY 10022-4731.

- ANDA 86-869; Nitrospan (controlled-release) Capsules containing 6.5 mg of nitroglycerin per capsule; Rhone-Poulenc Rorer.

- ANDA 87-229; Nitrobon (controlled-release) Capsules containing 2.5 mg nitroglycerin per capsule; Inwood Laboratories, Inc., Division of Forest Laboratories, Inc., 909 Third Ave., New York, NY 10022-4731.

- ANDA 87-544; Nitrobon (controlled-release) Capsules containing 6.5 mg nitroglycerin per capsule; Inwood Laboratories (formerly held by Ascot Hospital Pharmaceuticals, Inc.).

- ANDA 87-715; Nitrong (controlled-release) Tablets containing 9 mg nitroglycerin per tablet; Wharton Laboratories.

- ANDA 87-814; Nitro-Time (controlled-release) Capsules containing 2.5 mg nitroglycerin per capsule; Time-Cap Laboratories, 7 Michael Ave., Farmingdale, NY 11735.

- ANDA 87-815; Nitro-Time (controlled-release) Capsules containing 6.5 mg nitroglycerin per capsule; Time-Cap Laboratories.

- ANDA 87-816; Nitro-Time (controlled-release) Capsules containing 9 mg nitroglycerin per capsule; Time-Cap Laboratories.

- ANDA 87-975; Nitroglycerin Controlled-Release Capsules containing 2.5 mg of the drug per capsule; Eon Labs Manufacturing, Inc. (formerly held by The Vitarine Co.), 227-15 North Conduit Ave., Laurelton, NY 11413.

- ANDA 87-976; Nitroglycerin Controlled-Release Capsules containing 6.5 mg of the drug per capsule; Eon Labs Manufacturing.

- ANDA 88-435; Nitrocardin Sustained Action Capsules containing 2.5 mg nitroglycerin per capsule; Sidmak Laboratories, Inc., P.O. Box 371, East Hanover, NJ 07936.

- ANDA 88-436; Nitrocardin Sustained Action Capsules containing 6.5 mg nitroglycerin per capsule; Sidmak Laboratories.

- ANDA 88-437; Nitrocardin Sustained Action Capsules containing 9 mg nitroglycerin per capsule; Sidmak Laboratories.

- ANDA 88-509; Nitroglycerin Controlled-Release Capsules containing 9 mg of the drug per capsule; Eon Labs Manufacturing (formerly held by Phoenix Pharmaceutical, Inc.).

### III. Notice of Opportunity for a Hearing

On the basis of all the data and information available to her, the Director of the Center for Drug Evaluation and Research is unaware of any adequate and well-controlled clinical investigation, conducted by experts who are qualified by scientific training and experience, meeting the requirements of section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355), 21 CFR 314.126, and 21 CFR part 320 that demonstrates effectiveness (i.e., bioavailability/bioequivalence) of the drugs listed in section II of this document and that is in compliance with the conditions established in the September 7, 1984, and December 26, 1985, notices for continued marketing.

Therefore, notice is given to the holders of the NDA's and ANDA's listed in section II of this document and to all other interested persons that the Director of the Center for Drug Evaluation and Research proposes to issue an order under section 505(e) of the act withdrawing approval of the applications and all amendments and supplements thereto on the ground that new information before her with respect to the drug products, evaluated together with the evidence available to her when the applications were approved, shows there is a lack of substantial evidence that the drug products will have the effect they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in the labeling.

In addition to the holders of the applications specifically named previously, this notice of opportunity for hearing applies to all persons who manufacture or distribute a drug product, not the subject of an approved application, that is identical, related, or similar to a drug product named in section II of this document, as defined in § 310.6. It is the responsibility of every drug manufacturer or distributor to review this notice of opportunity for hearing to determine whether it covers any drug product that they manufacture or distribute. Such manufacturers or distributors may request an opinion of the applicability of this notice to a specific drug product by writing to the Division of Prescription Drug Compliance and Surveillance (address above).

This notice of opportunity for a hearing encompasses all issues relating to the legal status of the drug products subject to it (including identical, related, or similar drug products as defined in § 310.6), e.g., any contention that any such product is not a new drug

because it is generally recognized as safe and effective within the meaning of section 201(p) of the act (21 U.S.C. 3241(p)) or because it is exempt from part or all of the new drug provisions of the act under the exemption for products marketed before June 25, 1938, in section 201(p) of the act, or under section 107(c) of the Drug Amendments of 1962, or for any other reason.

In accordance with section 505 of the act and the regulations issued under it (parts 310 and 314 (21 CFR parts 310 and 314)), an applicant and all other persons subject to this notice are hereby given an opportunity for hearing to show why approval of the applications should not be withdrawn.

An applicant or any other person subject to this notice who decides to seek a hearing shall file: (1) On or before May 20, 1999, a written notice of appearance and request for hearing, and (2) on or before June 21, 1999, the data, information, and analyses relied on to demonstrate that there is a genuine issue of material fact to justify a hearing, as specified in § 314.200. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, a notice of appearance and request for a hearing, information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in §§ 314.150, 314.151, and 314.200 and in 21 CFR part 12.

The failure of an applicant or any other person subject to this notice to file a timely written notice of appearance and request for hearing, as required by § 314.200, constitutes an election by that person not to use the opportunity for a hearing concerning the action proposed and a waiver of any contentions concerning the legal status of that person's drug product(s). Any new drug product marketed without an approved new drug application is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that there is no genuine and substantial issue of fact which precludes the withdrawal of approval of the application, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing are to be filed in four copies. Except for data and information prohibited from public disclosure under section 301 of the act (21 U.S.C. 331(j)) or 18 U.S.C. 1905, the submissions may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under section 505 of the act and under authority delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.82).

Dated: April 13, 1999.

**Janet Woodcock,**

*Director, Center for Drug Evaluation and Research.*

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### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Health Care Financing Administration

[HCFA-R-70]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Type of Information Collection Request:** Extension of a currently approved collection;

**Title of Information Collection:** Information Collection Requirements in HSQ-110, Acquisition, Protection and Disclosure of Peer Review Organization Information and Supporting Regulations in 42 CFR, 476.104, 476.105, 476.116, and 476.134;