

ingredients, identified in § 331.11(c), must continue to bear both warnings required by § 330.1(g).

Because this final rule relates only to warnings for OTC antacid and antitflatulent drug products, the changes in the "exclusivity" policy that were recently published in the *Federal Register* of May 1, 1986 (51 FR 16258) do not apply to this document.

One comment was submitted in response to the agency's request for specific comment on the economic impact of this rulemaking (49 FR 14909). The comment argued that marketers of sodium bicarbonate products would suffer unjustifiable, irreparable economic harm if sodium bicarbonate products were required to bear the "keep out of reach of children" statement because the statement would deter consumers from purchasing the product for use as a refrigerator deodorant, baking ingredient, etc. Because this final rule exempts powder forms of sodium bicarbonate intended primarily for other than drug uses from the "keep out of reach of children" statement, the comment's concern is moot. The agency has examined the economic consequences of this final rule in conjunction with other rules resulting from the OTC drug review. In a notice published in the *Federal Register* of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this final rule for OTC antacid and antitflatulent drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act, Public Law 96-354. That assessment included a discretionary Regulatory Flexibility Analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC antacid and antitflatulent drug products is not

expected to pose such an impact on small businesses. Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects

21 CFR Part 331

Labeling, OTC drugs, Antacid drug products.

21 CFR Part 332

Labeling, OTC drugs, Antitflatulent drug products.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations is amended in Parts 331 and 332 as follows:

PART 331—ANTACID PRODUCTS FOR OVER-THE-COUNTER (OTC) HUMAN USE

1. The authority citation for 21 CFR Part 331 continues to read as follows:

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041-1042 as amended, 1050-1053 as amended, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); 5 U.S.C. 553; 21 CFR 5.11.

§ 331.11 [Amended]

2. In Part 331, § 331.11 *Listing of specific active ingredients* is amended in paragraph (k)(1) by revising the last sentence to read:

* * * * *

(k) * * *

(1) * * * That part of the warning required by § 330.1(g), which states, "Keep this and all drugs out of the reach of children" is not required on a product which contains only sodium bicarbonate powder and which is intended primarily for other than drug uses.

3. In Part 331, § 331.30 is amended by adding new paragraph (g) to read as follows:

§ 331.30 Labeling of antacid products.

* * * * *

(g) *Exemption from the general accidental overdose warning.* The labeling for antacid drug products containing the active ingredients identified in § 331.11(a), (b), and (d) through (m); permitted combinations of these ingredients provided for in

§ 331.10; and any of these ingredients or combinations of these ingredients in combination with simethicone (identified in § 332.10 of this chapter and provided for in § 331.15(c)), are exempt from the requirement in § 300.1(g) of this chapter that the labeling bear the general warning statement "In case of accidental overdose, seek professional assistance or contact a poison control center immediately." With the exception of sodium bicarbonate powder products identified in § 331.11(k)(1), the labeling must continue to bear the first part of the general warning in § 330.1(g) of this chapter, which states, "Keep this and all drugs out of the reach of children."

PART 332—ANTIFLATULENT PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

4. The authority citation for 21 CFR Part 332 continues to read as follows:

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041-1042 as amended, 1050-1053 as amended, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); 5 U.S.C. 553; 21 CFR 5.11.

5. In Part 332, § 332.30 is amended by adding new paragraph (c) to read as follows:

§ 332.30 Labeling of antitflatulent products.

* * * * *

(c) *Exemption from the general accidental overdose warning.* The labeling for antitflatulent drug products containing simethicone identified in § 332.10 and antacid/antitflatulent combination drug products provided for in § 332.15, containing the active ingredients identified in § 331.11(a), (b), and (d) through (m) of this chapter are exempt from the requirement in § 330.1(g) of this chapter that the labeling bear the general warning statement "In case of accidental overdose, seek professional assistance or contact a poison control center immediately." The labeling must continue to bear the first part of the general warning in § 330.1(g) of this chapter, which states, "Keep this and all drugs out of the reach of children."

Dated: May 3, 1986.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 86-17181 Filed 7-31-86; 8:45 am]

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Federal Register

Friday
August 1, 1986

Part VI

Department of Education

Availability of Grants for Experimental
and Innovative Training Program; Notice

DEPARTMENT OF EDUCATION**Office of Special Education and Rehabilitative Services****Experimental and Innovative Training Program; Availability of Grants**

AGENCY: Department of Education.

ACTION: Notice of final funding priority for fiscal year 1986.

SUMMARY: The Secretary announces an annual funding priority for training grants under the Experimental and Innovative Training Program in order to ensure effective use of program funds and to direct funds to an area of identified personnel need during fiscal year 1986. The Secretary will give an absolute preference to applications that meet the terms of the priority.

EFFECTIVE DATE: This final annual funding priority takes effect either 45 days after publication in the *Federal Register* or later if Congress takes certain adjournments. If you want to know the effective date of this final annual funding priority, call or write the Department of Education contact person.

FOR FURTHER INFORMATION CONTACT:

Delores L. Watkins, Division of Resource Development, Rehabilitation Services Administration, U.S. Department of Education, 400 Maryland Avenue, SW., (Room 3324-M/S 2312, Mary E. Switzer Building), Washington, D.C. 20202. Telephone: (202) 732-1332.

SUPPLEMENTARY INFORMATION: Grants for the Experimental and Innovative Training Program are authorized by Title III, section 304 of the Rehabilitation Act of 1973, as amended. Program regulations for the Experimental and Innovative Training Program are established at 34 CFR Part 387. The purpose of the Experimental and Innovative Training Program is to support projects designed to develop new types of rehabilitation personnel and to demonstrate the effectiveness of these new types of personnel in providing rehabilitation services to severely handicapped persons and to develop new and improved methods of training rehabilitation personnel to achieve more effective delivery of rehabilitation services by State and other rehabilitation agencies.

Summary of Comments and Responses

A notice of proposed annual funding priority was published in the *Federal Register* on May 21, 1986 (51 FR 18651) for the Experimental and Innovative Training Program. No comments were received in response to the Notice of Proposed Priority within the designated period for comment. No change has been made.

Final Priority

In accordance with the Education Department General Administrative Regulations (EDGAR) at 34 CFR 75.105(c)(3), the Secretary will give an absolute preference to applications submitted under the Experimental and

Innovative Training Program in fiscal year 1986 that respond to the priority described below. An absolute preference is one which permits the Secretary to select only those applications that meet the described priority.

All applications submitted under the Experimental and Innovative Training Program must address the training of rehabilitation counselors employed by State vocational rehabilitation agencies. State vocational rehabilitation agencies have only recently begun to serve learning disabled adults. It is essential, therefore, that rehabilitation counselors develop and maintain skills that will enable them to identify adults who are learning disabled, determine the eligibility of those individuals to receive rehabilitation services, and plan rehabilitation programs for and deliver services to learning disabled individuals. The training must also emphasize improved coordination of services between special education and vocational rehabilitation service providers and the effective use of resources in the community to facilitate the transition of learning disabled individuals from school to employment.

(Catalog of Federal Domestic Assistance No. 84.129, Rehabilitation Training)

(29 U.S.C. 774)

Dated: July 29, 1986.

William J. Bennett,

Secretary of Education.

[FR Doc. 86-17319 Filed 7-31-86; 8:45 am]

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Best of Federal Practice

Friday
August 1, 1986

Part VII

Department of Education

Office of Special Education and
Rehabilitation Services

Rehabilitation Long-Term Training
Program; Notice of Final Funding Priority
for Fiscal Year 1986

DEPARTMENT OF EDUCATION**Office of Special Education and Rehabilitation Services****Rehabilitation Long-Term Training Program****AGENCY:** Department of Education.**ACTION:** Notice of Final Funding Priority for Fiscal Year 1986.

SUMMARY: The Secretary announces an annual funding priority for long-term training grants in the field of Rehabilitation Workshop and Facility Personnel in order to ensure effective use of program funds and to direct funds to areas of identified need during fiscal year 1986. The Secretary will give an absolute preference to applications that meet the terms of the priority.

EFFECTIVE DATE: This final annual funding priority takes effect either 45 days after publication in the *Federal Register* or later if Congress takes certain adjournments. If you want to know the effective date of this final annual funding priority, call or write the Department of Education contact person.

FOR FURTHER INFORMATION CONTACT: Delores L. Watkins, Division of Resource Development, Rehabilitation Services Administration, U.S. Department of Education, 400 Maryland Avenue, SW., (Room 3324-M/S 2312,

Mary E. Switzer Building), Washington, DC 20202. Telephone: (202) 732-1332.

SUPPLEMENTARY INFORMATION: Grants for the Rehabilitation Training Program are authorized by Title III, section 304 of the Rehabilitation Act of 1973, as amended. Program regulations for the Rehabilitation Long-term Training Program are established at 34 CFR Part 386. The purpose of the Rehabilitation Long-term Training Program is to support projects designed to train personnel for employment in public and private agencies involved in the rehabilitation of physically and mentally disabled individuals, especially those who are severely disabled.

Summary of Comments and Responses

A notice of proposed annual funding priorities was published in the *Federal Register* on May 20, 1986 at 51 FR 18549. No letters of comment were received in response to the Notice of Proposed Priority. No change has been made.

Final Priority

In accordance with the Education Department General Administrative Regulations (EDGAR) at 34 CFR 75.105(c)(3), the Secretary will give an absolute preference to long-term training applications submitted in the field of Rehabilitation Workshop and Facility Personnel in fiscal year 1986 that respond to the priority described below. An absolute preference is one which

permits the Secretary to select only those applications that meet the described priority.

All applications submitted in the long-term training field of Rehabilitation Workshop and Facility Personnel must address the training of personnel who are employed by and provide direct rehabilitation services in vocationally oriented workshops and facilities. The training must focus on the development and upgrading of skills of such categorical types of workshop and facility personnel as vocational instructors, production supervisors and resident supervisors. The training must develop and upgrade the skills of such direct service delivery personnel to use new and innovative methods and techniques in the vocational rehabilitation of physically and mentally disabled individuals and their placement into competitive employment. The training must also increase the skills of those trained to provide transitional employment and supported employment services to disabled individuals.

(Authority: 29 U.S.C. 774)

(Catalog of Federal Domestic Assistance No. 84.129, Rehabilitation Training)

Dated: July 29, 1986.

William J. Bennett,
Secretary of Education.

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