of introducing SVD into the United States.

Therefore, we are proposing that pork and pork products, as well as any ship's stores, airplane meals, and baggage containing such pork, offered for importation into the United States from Germany be subject to the restrictions specified in § 94.13 of the regulations and to the applicable requirements contained in the regulations of the USDA's Food Safety and Inspection Service at 9 CFR chapter III. Section 94.13 requires, in part, that pork and pork products be: (1) Prepared in an inspected establishment that is eligible to have its products imported into the United States under the Federal Meat Inspection Act; and (2) accompanied by a foreign meat inspection certificate as well as a certification issued by a full-time salaried veterinary official of the national government of the exporting country, stating that certain precautions have been satisfied so that the pork or pork product has not been commingled with or exposed to animals, pork, or pork products originating in, or transported through, a country in which SVD is considered to exist.

Because hog cholera exists in Germany, the importation of pork and pork products from Germany would continue to be subject to the restrictions in § 94.9 for pork and pork products from countries where hog cholera exists. The importation of live swine, except for wild swine, from Germany would continue to be prohibited due to hog cholera, in accordance with § 94.10.

Executive Order 12866 and Regulatory Flexibility Act.

This proposed rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review process required by Executive Order 12866.

This proposed rule would amend the regulations in part 94 by adding Germany to the list of countries that have been declared free of SVD. This action would relieve certain restrictions on the importation of pork and pork products into the United States from Germany. However, other requirements would continue to restrict the importation of live swine and pork and pork products.

Because of the continued presence of hog cholera in Germany, nearly all of the current U.S. restrictions on the importation of pork and pork products would remain unchanged. The only area of pork importation that may be affected should Germany be declared free of SVD is cured and dried pork imports. A lengthy curing and drying period is required at present for pork and pork products originating from countries with SVD (see 9 CFR 94.17). The restriction for hog cholera is much shorter, requiring that the meat be thoroughly cured and fully dried for a period of not less than 90 days so that the product is shelf stable without refrigeration (see 9 CFR 94.9).

A shorter and less costly curing and drying period for pork and pork products could lead to Germany's increased participation in the U.S. market, depending on the competitiveness of the market for imported cured and dried pork and pork products. However, the impact for U.S. importers and consumers is not expected to be significant. In the fiscal year 1993–94, Germany exported 232 tons of prepared or preserved pork to the United States, which amounted to only 0.25 percent of the total quantity imported into the United States. The effect of this proposed rule on U.S. domestic prices or supplies or on U.S. businesses, including small entities, is expected to be negligible.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been approved by the Office of Management and Budget (OMB), and there are no new requirements. The assigned OMB control number is 0579–0015.

List of Subjects in 9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

Accordingly, 9 CFR part 94 would be amended as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), VELOGENIC VISCEROTROPIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, HOG CHOLERA, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

1. The authority citation for part 94 would continue to read as follows:

Authority: 7 U.S.C. 147a, 150ee, 161, 162, and 450; 19 U.S.C. 1306; 21 U.S.C. 111, 114a, 134a, 134b, 134c, 134f, 136, and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331, and 4332; 7 CFR 2.17, 2.51, and 371.2(d).

§ 94.12 [Amended]

2. In § 94.12, paragraph (a) would be amended by adding ''Germany,'' immediately after ''Finland,''.

§ 94.13 [Amended]

3. In § 94.13, the introductory text, the first sentence would be amended by adding ''Germany,'' immediately after ''Denmark,''.

Done in Washington, DC, this 22nd day of August 1995.

Lonnie J. King,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95–21288 Filed 8–28–95; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 95P–0003]

Food Labeling: Health Claims; Sugar Alcohols and Dental Caries; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a proposed rule that appeared in the **Federal Register** of July 20, 1995 (60 FR 37507). The document proposed to authorize the use, on food labels and in food labeling, of health claims on the association between sugar alcohols and the nonpromotion of dental caries and to exempt sugar alcohol-containing foods from certain provisions of the health claims general requirements regulation. The document was published with some errors. This document corrects those errors.

DATES: Written comments by October 3, 1995. The agency is proposing that any

final rule that may issue based upon this proposal become effective 30 days following its publication.

FOR FURTHER INFORMATION CONTACT: Joyce J. Saltsman, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5916.

In FR Doc. 95–17505, appearing on page 37507 in the **Federal Register** of Thursday, July 20, 1995, the following corrections are made:

1. On page 37510, in the second column, in the first paragraph, in line 6, the phrase ''and the FASEB'' is corrected to read ''of FASEB''.

2. On page 37511, in the first column, in the fourth paragraph, in the sixth line from the bottom of the paragraph, ''the 30-min (min) test'' is corrected to read ''the 30-minute (min) test''.

3. On page 37513, in the second column, in the first full paragraph, in line 20, the phrase ''just before to clinic visits.'' is corrected to read ''just before clinic visits.''

4. On page 37514, in the second column, in the second paragraph, in line 12, the phrase ''front of maxillary and'' is corrected to read ''front maxillary and''.

5. On page 37515, in the second column, in the first full paragraph, in line 7, the phrase ''whose parents consumed'' is corrected to read ''who consumed''.

6. On page 37520, in the second column, in the last paragraph, in line 1, the phrase ''In its March 1979, review'' is corrected by removing the comma after the date.

7. On page 37521, in the second column, in the second paragraph, in line 1, the phrase ''In its August 1979, review'' is corrected by removing the comma after the date.

8. On page 37527, in the third column, in reference 21, the name ''Bánózcy'' is corrected to read ''Bánóczy''.

9. On page 37529, in the first column, in reference 73, the word ''Carigenicity'' is corrected to read ''Cariogenicity''.

§ 101.80 [Corrected]

10. On page 37530, in the first column, in § 101.80 *Health claims: dietary sugar alcohols and dental caries*, in paragraph (c)(2)(i)(D), the phrase ''paragraph (C) of this section.'' is corrected to read ''paragraph (c)(2)(i)(C) of this section.''

Dated: August 23, 1995.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 95–21381 Filed 8–28–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 310 and 341

[Docket No. 95N–0205]

Rin 0905–AA06

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of Monograph for OTC Bronchodilator Drug Products; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to September 27, 1995, the period for comments for the notice of proposed rulemaking to amend the monograph for over-the-counter (OTC) bronchodilator drug products that was published in the **Federal Register** of July 27, 1995. That document proposed to remove the ingredients ephedrine, ephedrine hydrochloride, ephedrine sulfate, and racephedrine hydrochloride from the final monograph for OTC bronchodilator drug products and to classify these ingredients as not generally recognized as safe and effective for OTC use. FDA is taking this action in response to several requests to extend the period for comments to allow interested persons adequate time to assess and respond to the proposal.

DATES: Written comments by September 27, 1995.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 27, 1995 (60 FR 38643), FDA published a notice of proposed rulemaking to amend the final monograph for OTC bronchodilator drug products to remove the ingredients ephedrine, ephedrine hydrochloride, ephedrine sulfate, and racephedrine hydrochloride and to classify these ingredients as not generally recognized as safe and effective for OTC use. Interested persons were given until August 28, 1995 to submit comments on the proposal.

In the proposal, the agency indicated that these ingredients should no longer be included in the final monograph for OTC bronchodilator drug products based on their extensive use in illicit drug manufacture and their potential for causing harm as a result of misuse and abuse. This proposed amendment to the monograph, if finalized, would remove these ingredients from the OTC market whether present as single ingredient products or in combination with other cough-cold ingredients.

FDA has received requests from a manufacturers' association and two manufacturers of OTC bronchodilator drug products to extend the comment period until October 27, 1995, to permit adequate development of comments by industry and other interested parties. The requests stated that the extension is necessary because of the summer vacation season and the inability to develop a responsive submission in 30 days as provided in the proposed monograph amendment.

One comment indicated that FDA's action could set a precedent for the agency to take action later concerning OTC drug products containing pseudoephedrine and phenylpropanolamine, which are also included in the Domestic Chemical Diversion Control Act of 1993 as ≥listed chemicals≥ used as precursors in the clandestine manufacture of methamphetamine and metcathinone. The comment added that because the proposed amendment to the monograph could have profound implication on the entire OTC drug industry, additional time to comment is necessary to evaluate the legal and policy implications for companies who make products containing pseudoephedrine and/or phenylpropanolamine.

FDA emphasizes that this proposal affects ephedrine ingredients only. The proposed amendment does not affect the current OTC marketing status of pseudoephedrine or phenylpropanolamine in any manner. However, because of the comment's concerns that the proposal may have a potential future impact on the OTC drug industry, the agency wants to allow additional time for interested persons and manufacturers to more fully express their views. However, because of the continuing misuse and abuse of OTC ephedrine drug products, the agency has determined that the additional period shall be 30 days only. Therefore, the agency is providing an extension of the period for comments until September 27, 1995.

Interested persons may, on or before September 27, 1995, submit to the Dockets Management Branch (address above) written comments on the proposed monograph amendment.