"nitrate" includes sodium nitrate ($NaNO_3$) and potassium nitrate (KNO_3). To assure safe use of such ingredients, the labeling of the premixes shall bear instructions to the user that such separately packaged ingredients are not to be combined until just before use. Encapsulating or coating some or all of the ingredients does not constitute separate packaging.

2. By adding new § 170.70 to read as follows:

§ 170.70 Nitrates and nitrites in poultry products.

The Food and Drug Administration has determined that no prior sanction or approval granted under the Federal Food, Drug, and Cosmetic Act, within the meaning of section 201(s)(4) of that act (21 U.S.C. 321(s)(4)), exists for the use of nitrates or nitrites in the manufacture of poultry products. As used in this section, the term "nitrate" includes sodium nitrate ($NaNO_3$) (also known as soda niter, nitrate of soda, and chile saltpeter) and potasium nitrate (KNO_3) (also known as saltpeter and nitrate of potash). Similarly, the term "nitrite" includes sodium nitrite ($NaNO_2$) and potasium nitrite (KNO_2).

Interested persons may, on or before February 19, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order.

Dated: December 13, 1979.

Jere E. Goyan,

Commissioner of Food and Drugs.

[FR Doc. 79–38935 Filed 12–17–79; 10:30 am]

BILLING CODE 4110–03–M

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21 CFR Part 357

[Docket No. 79N–0379]

Exocrine Pancreatic Insufficiency Drug Products for Over-the-Counter Human Use; Establishment of a Monograph; Notice of Proposed Rulemaking

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish conditions under which over-the-counter (OTC) exocrine pancreatic insufficiency drug products are generally recognized as safe and effective and not misbranded. Exocrine pancreatic insufficiency drug products are used to compensate for the insufficient secretion of pancreatic enzymes important to the digestive process. The proposed rule, based on the recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products, is part of the ongoing review of OTC drug products conducted by the Food and Drug Administration (FDA).

DATES: Comments by March 20, 1980; reply comments by April 21, 1980.

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFD–510), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4960.

SUPPLEMENTARY INFORMATION: In accordance with Part 330 (21 CFR Part 330), FDA received on November 19, 1978, a report of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products. Under § 330.10(a)(6) (21 CFR 330.10(a)(6)), the Commissioner of Food and Drugs issues (1) a proposed regulation containing the monograph recommended by the Panel, which establishes conditions under which OTC drugs are generally recognized as safe and effective and not misbranded (i.e., Category I); (2) a statement of the conditions excluded from the monograph because the Panel determined that they would result in the drugs not being generally recognized as safe and effective or would result in misbranding (i.e., Category II); (3) a statement of the conditions excluded from the monograph because the Panel determined that the available data are insufficient to classify those conditions under either (1) or (2) above (i.e., Category III); and (4) the conclusions and recommendations of the Panel. The Panel's conclusions on exocrine pancreatic insufficiency drug products contained no Category III conditions.

The unaltered conclusions and recommendations of the Panel are issued to stimulate discussion, evaluation, and comment on the full sweep of the Panel's deliberations. The report has been prepared independently of FDA, and the agency has not yet fully evaluated the report. The Panel's findings appear in this document as a formal proposal to obtain public comment before the agency reaches any decision on the Panel's recommendations. This document represents the best scientific judgment of the Panel members, but does not necessarily reflect the agency's position on any particular matter contained in it. After FDA has carefully reviewed all comments submitted in response to this proposal, the agency will issue a tentative final regulation in the Federal Register to establish a monograph for OTC exocrine pancreatic insufficiency drug products.

In accordance with § 330.10(a)(2) (21 CFR 330.10(a)(2), the Panel and FDA have held as confidential all information concerning OTC exocrine pancreatic insufficiency drug products submitted for consideration by the Advisory Review Panel. All this information will be put on public display at the office of the Hearing Clerk, Food and Drug Administration, after January 21, 1980, except to the extent that the person submitting it demonstrates that it still falls within the confidentiality provisions of 18 U.S.C. 1905 or section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)). Requests for confidentiality should be submitted to William E. Gilbertson, Bureau of Drugs (HFD–510) (address given above).

Based upon the conclusions and recommendations of the Panel, FDA proposes the following:

1. That the conditions included in the monograph, under which the drug products would be generally recognized as safe and effective and not misbranded (Category I), be effective 30 days after the date of publication of the final monograph in the Federal Register.

2. That the conditions excluded from the monograph because they would cause the drug to be not generally recognized as safe and effective or to be misbranded (Category II), be eliminated from OTC drug products effective 6 months after the date of publication of the final monograph in the Federal Register, regardless of whether further testing is undertaken to justify their future use.

A proposed review of the safety, effectiveness, and labeling of all OTC drugs by independent advisory review panels was announced in the Federal Register of January 5, 1972 (37 FR 85). The final regulations providing for this OTC drug review under § 330.10 were published and made effective in the Federal Register of May 11, 1972 (37 FR 9464). In accordance with these regulations, a request for data and information on all active ingredients

used in OTC miscellaneous internal drug products was issued in the **Federal Register** of November 16, 1973 (38 FR 31696). In the **Federal Register** of August 27, 1975 (40 FR 38179) a further notice supplemented the initial notice with a detailed list of ingredients included in OTC miscellaneous drug products.

The Commissioner appointed the following Panel to review the information submitted and to prepare a report under § 330.10(a) (1) and (5) on the safety, effectiveness and labeling of the ingredients in those products:

John W. Norcross, M.D., Chairman
Ruth Eleanor Brown, R.Ph. (resigned May 1976)
Elizabeth C. Giblin, Ed.D.
Richard D. Harshfield, M.D.
Theodore L. Hyde, M.D.
Claus A. Rohweder, D.O.
Samuel O. Thier, M.D. (resigned November 1976)
William R. Arrowsmith, M.D. (appointed March 1976)
Diana F. Rodriguez-Calvert, Pharm.D. (appointed July 1976)

Representatives of consumer and industry interests served as nonvoting members of the Panel. Eileen Hoates, nominated by the Consumer Federation of America, served as the consumer liaison until September 1975, followed by Michael Schulman, J.D. Francis J. Hailey, M.D., served as the industry liaison, and in his absence John Parker, Pharm.D., served. Dr. Hailey served until June 1975, followed by James M. Holbert, Sr., Ph.D. All industry liaison members were nominated by the Proprietary Association.

The following FDA employees assisted the Panel: Armond M. Welch, R.Ph., served as the Panel Administrator. Enrique Fefer, Ph.D., served as the Executive Secretary until July 1976, followed by George W. James, Ph.D., until October 1976, followed by Natalia Morgenstern until May 1977, followed by Arthur Auer. Joseph Hussion, R.Ph., served as the Drug Information Analyst until July 1976, followed by Anne Eggers, R.Ph., M.S., until October 1977, followed by John R. Short, R.Ph.

In order to expand its medical and scientific base, the Panel called upon Ralph B. D'Agostino, Ph.D. (statistics), as a consultant for advice in areas which required particular expertise.

The Advisory Review Panel on OTC Miscellaneous Internal Drug Products was charged with the review of many categories of drugs. Due to the large number of ingredients and varied labeling claims, the Panel decided to review and publish its findings separately for several drug categories and individual drug products. The Panel presents its conclusions and recommendations for exocrine pancreatic insufficiency drug products in this document. This Panel also reviewed the ingredients in these drug products for different labeling claims in another document entitled "OTC Digestive Aid Drug Products," which will be published in a future issue of the **Federal Register**. The review of other categories of miscellaneous internal drug products will be continued by the Panel, and its findings will be published periodically in future issues of the **Federal Register**.

The Panel was first convened on January 13, 1975 in an organizational meeting. Working meetings were held on the following dates (the dates of those meetings which dealt with the topic of this document are in italics): *February 23 and 24, March 23 and 24,* April 27 and 28, June 22 and 23, September 21 and 22, and November 16 and 17, 1975; February 8 and 9, March 7 and 8, April 11 and 12, May 9 and 10, July 11 and 12, and *October 10 and 11,* 1976; *February 20 and 21, April 3 and 4,* May 15 and 16, July 9, 10, and 11, *October 15, 16, and 17,* and *December 2, 3, and 4,* 1977; *January 28, 29, and 30,* March 10, 11, and 12, May 5, 6, and 7, *June 23, 24, and 25, August 4, 5, and 6, September 29, 30, and October 1,* and *November 17, 18, and 19,* 1978.

The minutes of the Panel meetings are on public display in the office of the Hearing Clerk (HFA–305), Food and Drug Administration (address given above).

No person requested an opportunity to appear before the Panel to express his or her views on exocrine pancreatic insufficiency drug products.

The Panel has thoroughly reviewed the literature and data submissions and has considered all pertinent information submitted through November 19, 1978, in arriving at its conclusions and recommendations.

In accordance with the OTC drug review regulations (21 CFR 330.10), the Panel considered OTC drug products to treat exocrine pancreatic insufficiency with respect to the following three categories:

Category I. Conditions under which OTC drug products to treat exocrine pancreatic insufficiency are generally recognized as safe and effective and are not misbranded.

Category II. Conditions under which OTC drug products to treat exocrine pancreatic insufficiency are not generally recognized as safe and effective or are misbranded.

Category II. Conditions for which the available data are insufficient to permit final classification at this time.

A. Submission of Data and Information

Pursuant to the notices published in the **Federal Register** of November 16, 1973 (38 FR 31696) and August 27, 1975 (40 FR 38179) requesting the submission of data and information on OTC miscellaneous internal drug products, the following firms made submissions for products used in treating exocrine pancreatic insufficiency.

1. *Submissions by firms.*

Firms and marketed products

Parke-Davis & Co., Detroit, MI 48232.—Panteric capsules, Panteric tablets, Panteric granules.
Hoechst-Roussel Pharmaceuticals, Inc., Somerville, NJ 08876.—Festal tablets.

2. *Classification of ingredients*—a. *Labeled active ingredients contained in marketed OTC exocrine pancreatic insufficiency drug products submitted to the Panel.*

Hemicellulase
Pancreatin

b. *Labeled active ingredients contained in marketed OTC exocrine pancreatic insufficiency drug products which were not submitted but were reviewed by the Panel.*

Pancrelipase

B. Referenced OTC Volumes

The "OTC Volumes" cited throughout this document include submissions made by interested persons in response to the call-for-data notices published in the **Federal Register** of November 16, 1973 (38 FR 31696) and August 27, 1975 (40 FR 38179). All of the information included in these volumes, except for those deletions which are made in accordance with the confidentiality provisions set forth in § 330.10(a)(2), will be put on display after January 21, 1980 in the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

C. General Discussion

Under normal circumstances the pancreas secretes a sufficient amount of ensymes into the intestine to account for a major portion of the digestive process. When the pancreas is not functioning properly or is partially removed surgically, lesser amounts of pancreatic digestive enzymes (e.g., lipase for fat digestion, protease for protein digestion, and amylase for starch digestion) are released into the intestine. Because the pancreas has a large functional reserve capacity, malabsorption (due to insufficient digestion) does not occur until the pancreatic enzyme output is reduced by more than 90 percent (Ref. 1), at which point the condition can usually be suspected by the increased fat content in the stool (steatorrhea). For the purpose of this document the Panel,

therefore, defines exocrine pancreatic insufficiency as a condition which requires diagnosis by a physician and in which the symptoms are due to inadequate exocrine pancreatic secretion.

For many years this condition has been effectively treated by the administration of pancreatic preparations consisting of varying proportions of lipase, protease, and amylase activity. The Panel considers these preparations acceptable only when all three of the components are combined into a single dosage form.

According to the National Formulary (N.F.) XIV, pancreatin contains, in each milligram (mg), not less than 25 N.F. Units of amylase activity, not less than 2.0 N.F. Units of lipase activity, and not less than 25 N.F. Units of protease activity. Pancreatin of a higher digestive power may be labeled as a whole-number multiple of the three minimum activities, e.g., the term "triple strength pancreatin" indicates that the preparation contains three times the activity of each enzyme per mg. Pancrelipase, also listed in N.F. XIV, contains, in each mg, not less than 100 N.F. Units of amylase activity, not less than 24 N.F. Units of lipase activity, and not less than 100 N.F. Units of protease activity. The N.F. Units of activity for pancreatin and pancrelipase are defined in the N.F. (Refs. 2 and 3).

With regard to labeling, the Panel has carefully reviewed the submitted labeling claims and has categorized them according to their acceptability. The Panel is aware that there may be other terms that would be acceptable in expressing the same Category I indications.

References

(1) Graham, D. Y., "Enzyme Replacement Therapy of Exocrine Pancreatic Insufficiency in Man," *The New England Journal of Medicine*, 23:1314–1317, 1977.

(2) "The National Formulary," 14th Ed., American Pharmaceutical Association, Washington, DC, pp. 519–521, 1975.

(3) "The National Formulary," 14th Ed., American Pharmaceutical Association, Washington, DC, pp. 523–525, 1975.

D. Combination Policy

The Panel has reviewed FDA's general combination policy on OTC drug products (21 CFR 330.10(a)(4)(iv)) and concurs with this policy for this condition.

This policy is as follows:

An OTC drug may combine two or more safe and effective active ingredients and may be generally recognized as safe and effective when each active ingredient makes a contribution to the claimed effect(s); when combining of the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients; and when the combination, when used under adequate directions for use and warnings against unsafe use, provides rational concurrent therapy for a significant proportion of the target population.

The Panel insists that all combination products which are used to treat exocrine pancreatic insufficiency must conform to all three requirements of this general combination policy. At the present time, no combination product has been submitted to the Panel, nor is the Panel aware of any such combination product which would satisfy the above requirements.

E. Category I Conditions for Exocrine Pancreatic Insufficiency Drug Products

The following are Category I conditions under which drug products used for the treatment of exocrine pancreatic insufficiency are generally recognized as safe and effective and are not misbranded.

1. *Category I active ingredients—pancreatin or pancrelipase.* The Panel concludes that pancreatin preparations (panreatin or pancrelipase) are generally recognized as safe and effective for OTC use in treating conditions of physician-diagnosed exocrine pancreatic insufficiency in the dosage noted below.

a. *Safety.* The Panel has determined that pancreatin preparations (pancreatin or pancrelipase) are safe in the usual recommended daily dosage of up to 14 grams (g) of triple-strength pancreatin when given in divided doses (Ref. 1). Side effects of nausea, vomiting, and diarrhea may occur at high doses (Ref. 1). Since pancreatin preparations are usually obtained from hogs, they should not be used by those individuals allergic to pork. The Panel recommends that the product labeling for pancreatin preparations contain a warning against to the use of such products by individuals allergic to pork.

b. *Effectiveness.* The pancreatic enzymes are collectively known as pancreatin. Pancreatin is an amorphous substance obtained from fresh hog pancreas. It contains principally amylase, protease, and lipase (Ref. 1) Pancrelipase is obtained in a similar manner; it differs from pancreatin mainly in that it has a higher lipase concentration. Both pancreatin and pancrelipase are employed in the treatment of conditions in which the secreation of pancreatic enzymes is deficient. In the absence of adequate pancreatic enzymes, the patient is unable to properly digest food; and, as a result stools contain excessive amount of undigested foodstuff, expecially fats which lead to steatorrhea, diarrhea, and malnutrition. Pancreatic enzymes, taken by mouth with meals, are effective in controlling these conditions when due to decreased pancreatic secreation (Refs. 2 through 7). However, it should be noted that the pancreas has such a large capacity to produce and secrete the necessary enzymes that, except in patients who have had excessively fatty meals, symptoms of pancreatic insufficiency are rarely noted even when 75 to 80 percent of that organ is removed (Ref. 2).

Although pancreatic enzymes taken by mouth are rapidly inactivated by pepsin in the high acidity of normal gastric juice (Ref. 8), gastric acidity is usually markedly reduced in patients with exocrine pancreatic insufficiency (Ref. 2). Pancreatic enxymes in enteric-coated preparations (designed for release and absorption in the intestines) may be less effective than preparations without such coating (Ref. 2).

The Panel concludes that both pancreatin and pancrelipase are generally recognized as effective for OTC use in treating physician-diagnosed exocrine pancreatic insufficiency.

c. *Dosage.* The Panel concludes that pancreatin preparations (pancreatin or pancrelipase) for OTC use in conditions of prediagnosed exocrine pancreatic insufficiency are safe and effective in the usual and recommended daily dose of up to 14 g of triple-strength pancreatin, or its equivalent, when given in divided doses with meals as recommended by the physician. The proportional activity of amylase, lipase, and protease may vary in these preparations.

d. *Labeling.* The Panel recommends Category I labeling for ingredients used to treat conditions of exocrine pancreatic insufficiency. (See paragraph E.2. below—Category I labeling.)

2. *Category I labeling.* The Panel recommends the following Category I labeling for drug products used to treat exocrine pancreatic insufficiency as being generally recognized as safe and effective and not misbranded:

a. *Indication.* "For the treatment of exocrine pancreatic insufficiency when conducted under the care of a physician."

b. *Warning.* For preparations obtained from pork the following warning should be used: "If you are allergic to pork, do not take this product."

References

(1) AMA Drug Evaluation, 3d Edition, Publishing Sciences Group, Inc., Littleton, MA, pp. 1085–1086, 1977.

(2) Graham, D. Y., "Enzyme Replacement Therapy of Exocrine Pancreatic Insufficiency in Man," *The New England Journal of Medicine*, 23:1314–1317, 1977.

(3) Littman, A., and D. H. Handscom, "Pancreatic Extracts," *The New England Journal of Medicine*, 281:201–204, 1969.

(4) Kalser, M. H., C. A. Leite, and W. D. Warren, "Fat Assimilation After Massive Distal Pancreatectomy," *The New England Journal of Medicine*, 279:570–576, 1968.

(5) Marks, I. N., S. Bank, and E. M. Airth, "Pancreatic Replacement Therapy in the Treatment of Pancreatic Steatorrhea, "*Gut*, 4: 217–22, 1963.

(6) Jordan, P. H., and M. I. Grossman, "Effect of Dosage Schedule on the Efficacy of Substitution Therapy in Pancreatic Insufficiency," *Gastroenterology*, 36:447–451, 1959.

(7) Marks, I. N., and S. Bank, "Treatment of Steatorrhea Due to Pancreatic Insufficiency," *Modern Treatment*, 2:326–334, 1965.

(8) Heizer, W. D., C. R. Cleaveland, and F. L. Iber, "Gastric Inactivation of Pancreatic Supplements," *Bulletin of the Johns Hopkins Hospital*, 116:261–270, 1965.

F. Category II Conditions for Exocrine Pancreatic Insufficiency Drug Products.

The following are Category II conditions under which drug products used for the treatment of exocrine pancreatic insufficiency are not generally recognized as safe and effective or are misbranded.

1. *Category II active ingredient—hemicellulase.* The Panel concludes that hemicellulase is safe for OTC use in the dose noted below, but it is not generally recognized as effective in treating exocrine pancreatic insufficiency.

a. *Safety.* No safety data were submitted. Hemicellulase is obtained from molds such as *Aspergillus oryzae* and *Penicillium notatum* as well as from various other sources (Refs. 1 and 2). Hemicellulase has been utilized as a digestive aid in the intestinal tract in the usual doses of 50 to 100 mg three times daily (Refs. 3 and 4). The Panel concludes that it is safe when used to treat exocrine pancreatic insufficiency in these doses.

b. *Effectiveness.* Hemicellulase is capable of hydrolyzing hemicellulose contained in ingested food plants. However, it has no relationship to the pancreatic enzymes, and it has not been demonstrated to be of value in the treatment of exocrine pancreatic insufficiency.

c. *Evaluation.* The Panel concludes that hemicellulase is generally recognized as safe for OTC use in the dose specified, but its effectiveness has not been demonstrated in treating exocrine pancreatic insufficiency.

2. *Category II labeling.* The following indications require close physician supervision and are, therefore, classified as Category II labeling for OTC use.

a. "Enteritis."

b. "Postgastrectomy syndrome."

c. "Chronic hepatitis."

d. "Gall-bladder disease."

e. "Surgical patients following cholecystectomy, subtotal gastrectomy, and other surgery of the upper gastrointestinal tract, except pancreatectomy."

References

(1) Pigman, W., "Enzymes Acting on Hemicelluloses, Gum, and Wood," *in* "The Enzymes," Vol. 1, Edited by Sumner, J. B., and K. Myrback, Academic Press, New York, pp. 739–744, 1951.

(2) Courtois, J. E., "Some Biochemical Aspects of Cellulases and Hemicellulases," *Glasnik Hemijskog Drugstvaw*, 32:365–388, 1967.

(3) OTC Volume 170034.

(4) OTC Volume 170144.

The Food and Drug Administration has determined that this document is exempt from the requirement of preparing an Environmental Impact Statement as specified under 21 CFR 25.1(f)(4).

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 701, 52 Stat. 1040–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321, 352, 355, 371)), and the Administrative Procedure Act (secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)), and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations be amended by adding to Part 357 a new Subpart E to read as follows:

PART 357—MISCELLANEOUS INTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart E—Exocrine Pancreatic Insufficiency Drug Products

Sec.

Authority: Secs. 201, 502, 505, 701, 52 Stat. 1040–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321, 352, 355, 371); (5 U.S.C. 553, 554, 702, 703, 704).

Subpart E—Exocrine Pancreatic Insufficiency Drug Products

§ 357.401 Scope.

An over-the-counter exocrine pancreatic insufficiency drug product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this subpart, in addition to each of the general conditions established in § 330.1 of this chapter.

§ 357.403 Definition.

Exocrine pancreatic insufficiency. A condition in which the symptoms are due to inadequate exocrine pancreatic secretion as diagnosed by a physician.

§ 357.410 Exocrine pancreatic insufficiency active ingredients.

The active ingredient of the product consists of any one of the following when used within the dosage limits established:

(a) Pancreatin.

(b) Pancrelipase.

§ 357.450 Labeling of exocrine pancreatic insufficiency drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as one which treats exocrine pancreatic insufficiency.

(b) *Indications.* The labeling of the product contains a statement of the indications under the heading "Indications" that is limited to the phrase: "For the treatment of exocrine pancreatic insufficiency when conducted under the care of a physician."

(c) *Warning.* The labeling of the product contains the following warning under the heading "Warnings": "If you are allergic to pork, do not take this product."

(d) *Directions*—(1) *For products containing Pancreatin, N.F. XIV.* The daily dose is up to 42 grams when given in divided doses with meals as recommended by a physician.

(2) *For products containing Pancrelipase, N.F. XIV.* The daily dose is up to 3.5 grams when given in divided doses with meals as recommended by a physician.

Interested persons are invited to submit their comments in writing (preferably in four copies and identified with the Hearing Clerk docket number found in brackets in the heading of this document) regarding this proposal on or before March 20, 1980. Comments should be addressed to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, and may be accompanied by a supporting memorandum or brief. Comments replying to comments may also be submitted on or before April 21, 1980. Comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed,

and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration

Dated: December 13, 1979.

William F. Randolph.

Acting Associate Commissioner for Regulatory Affairs

[FR Doc. 79-39110 Filed 12-20-79; 8:45 am]

BILLING CODE 4110-03-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[EE-150-78; EE-101-78]

Reasonable Funding Methods; Amortization of Experience Gains by Pension Plans Funded by Group Deferred Annuity Contracts; Public Hearings on Proposed Regulations

AGENCY: Internal Revenue Service, Treasury.

ACTION: Public hearings on proposed regulations.

SUMMARY: This document provides notice of public hearings on proposed regulations relating to reasonable funding methods and proposed regulations relating to amortization of experience gains by pension plans funded by group deferred annuity contracts.

DATES: The public hearings will be held on February 21, 1980, beginning at 10:00 a.m. Outlines of oral comments must be delivered or mailed by February 7, 1980.

ADDRESS: The public hearings will be held in the I.R.S. Auditorium, Seventh Floor, 7400 Corridor, Internal Revenue Building, 1111 Constitution Avenue, N.W., Washington, D.C. The outlines for oral comments on the proposed regulations relating to reasonable funding methods, should be submitted to the Commissioner of Internal Revenue, Attn: CC:LR:T (EE-150-78), Washington, D.C. 20224. The outlines for oral comments on the proposed regulations relating to the determination of actuarial cost under the minimum funding standards should be submitted to the Commissioner of Internal Revenue, Attn: CC:LR:T (EE-101-78), Washington, D.C. 20224.

FOR FURTHER INFORMATION CONTACT: George Bradley or Charles Hayden of the Legislation and Regulations Division, Office of Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, N.W., Washington, D.C. 20224, 202-566-3935, not a toll-free call.

SUPPLEMENTARY INFORMATION: The subjects of the public hearings are:

1. Proposed regulations relating to reasonable funding methods under section 412(c)(3) of the Internal Revenue Code of 1954, and section 3(31) of the Employee Retirement Income Security Act of 1974. These proposed regulations appeared in the **Federal Register** for Friday, October 5, 1979 (44 FR 57423).

2. Proposed regulations relating to the determination of actuarial cost under the minimum funding standards under section 412(b)(3) of the Internal Revenue Code of 1954. These proposed regulations appeared in the **Federal Register** for Friday, December 29, 1978 (43 FR 60964).

The rules of § 601.601 (a)(3) of the "Statement of Procedural Rules" (26 CFR Part 601) shall apply with respect to the public hearings. Persons who have submitted written comments within the time prescribed in the respective notices of proposed rulemaking and who desire to present oral comments at the respective hearing on such proposed regulations should submit an outline of the comments to be presented at the hearing and the time they wish to devote to each subject by February 7, 1980. Each speaker will be limited to 10 minutes for an oral presentation on each of the above listed proposed regulations for which timely comments have been submitted, exclusive of time consumed by questions from the panel for the Government and answers to these questions.

Because of controlled access restrictions, attendees cannot be admitted beyond the lobby of the Internal Revenue Building until 9:45 a.m.

An agenda showing the scheduling of the speakers will be made after outlines are received from the speakers. Copies of the agenda will be available free of charge at the hearing.

This document does not meet the criteria for significant regulations set forth in paragraph 8 of the Treasury Directive appearing in the **Federal Register** for Wednesday, November 8, 1978.

By direction of the Commissioner of Internal Revenue.

George H. Jelly,

Director, Employee Plans and Exempt Organizations Division.

[FR Doc. 39228 Filed 12-20-79; 8:45 am]

BILLING CODE 4830-01-M

26 CFR Parts 1, 16, 17, and 160

[LR-71-78]

Vinson-Trammell Act; Excess Profits on Contracts for Naval Vessels or Military Aircraft

AGENCY: Internal Revenue Service, Treasury.

ACTION: Extension of Time for Comments and Requests for a Public Hearing.

SUMMARY: This document provides notice of an extension of time for submitting comments and requests for a public hearing concerning the notice of proposed rulemaking with respect to the Vinson-Trammell Act; Excess Profits on Contracts for Naval Vessels or Military Aircraft. The extended deadline for submission of comments and requests for a public hearing is February 26, 1980.

DATES: Written comments and requests for a public hearing must be delivered or mailed by February 26, 1980.

ADDRESS: Send comments and requests for a public hearing to Commissioner of Internal Revenue, Attn: CC:LR:T (LR-71-78), Washington, D.C. 20224.

FOR FURTHER INFORMATION CONTACT: H. Benjamin Hartley of the Legislation and Regulations Division, Office of Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, D.C. 20224, CC:LR:T, 202-566-3287, not a toll-free call.

SUPPLEMENTARY INFORMATION: By a notice of proposed rulemaking published in the **Federal Register** for Friday, October 26, 1979 (44 FR 61611), comments and requests for a public hearing with respect to the proposed rules were to be delivered or mailed to the Commissioner of Internal Revenue, Attention: CC:LR:T (LR-71-78), Washington, D.C. 20224, by December 26, 1979. The date by which comments or requests must be delivered or mailed is hereby extended to February 26, 1980.

Note.—This document does not meet the criteria for significant regulations set forth in paragraph 8 of the Treasury Directive appearing in the **Federal Register** for Wednesday, November 8, 1978.

By direction of the Commissioner of Internal Revenue.

Robert A. Bley,

Director, Legislation and Regulations Division.

[FR Doc. 79-39227 Filed 12-20-79; 8:45 am]

BILLING CODE 4830-01-M