reports by that Act shall submit nonpublic statements of employment and financial interests containing the information required by the formats prescribed by the Office of Personnel Management.

34. In § 5.32 paragraphs (a), (c), and (d) are revised, paragraphs (f), (g), (h), and (i) are redesignated as (g), (h), (i), and (j) and a new paragraph (f) is added to read as follows:

§ 5.32 Employees required to submit statements.

(a) The following employees, whether or not serving in an acting capacity, shall submit statements to the Executive Director:

(1) The Secretary of the Commission;
(2) The Director of the Office of Policy Planning;
(3) The Director and Deputy Director of the Office of Public Information;
(4) The General Counsel;
(5) The Director of the Bureau of Competition;
(6) The Director of the Bureau of Consumer Protection;
(7) The Director of the Bureau of Economics;
(8) The Chief Administrative Law Judge;
(9) The Chief Presiding Officer;
(10) The Deputy Executive Director;
(11) The Director of Equal Employment Opportunity;
(12) The Director, Office of Congressional Relations;
(13) The Assistant to the Executive Director;
(14) Directors of the Regional Offices;
(15) Advisors to the Commissioners and the Assistant to the Chairman, except that each Commissioner in the Commissioner's discretion may direct otherwise.

* * * * *

(c) The following employees of the Bureaus of Competition, Consumer Protection and Economics, whether or not serving in an acting capacity, shall submit statements to their Bureau Director:

(1) Deputy Directors;
(2) Assistant Directors;
(3) Deputy Assistant Directors;
(4) Associate Directors;
(5) Executive Assistants to the Director and Assistants to the Director;
(6) Assistants to the Deputy Director.

(d) The following employees, whether or not serving in an acting capacity, shall submit statements to the Deputy Executive Director:

(1) The Director of the Division of Administrative Services;
(2) The Director of the Division of Budget and Finance;
(3) The Director of the Data Processing and Information Systems Division;
(4) The Director of the Division of Personnel;
(5) The Director of the Library; and
(6) The Director of the Office of Procurement and Contracts.

* * * * *

(f) Presiding Officers designated under § 1.13(c) of Part 1 shall submit statements to the Chief Presiding Officer.

§ 5.32 [Amended]

35. Section 5.32(i), redesignated from paragraph (h), is amended by changing "Civil Service Commission" to read "Office of Personnel Management."

§ 5.39 [Amended]

36. Section 5.39(b) is amended by changing "Assistant Executive Director for Management" to read "Deputy Executive Director," and by inserting after "Chief Administrative Law Judge," the phrase "the Chief Presiding Officer."

§ 5.40 [Amended]

37. Section 5.40 is amended by changing "Civil Service Commission" to read "Office of Personnel Management."

By direction of the Commission.

Carol M. Thomas,

Secretary.

[FR Doc. 81-14228 Filed 5-11-81; 8:45 am]

BILLING CODE 6750-01-M

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16 CFR Part 4

Participation in Commission Proceedings; Former Commission Members and Employees

AGENCY: Federal Trade Commission.

ACTION: Final rule.

SUMMARY: The Federal Trade Commission is revising its rule governing participation in Commission proceedings by former Commission members and employees. The wording of the prior rule produced uncertainty about when the rule applied and what the standards for decisionmaking were. The revised rule clarifies the circumstances under which former members and employees must file an application for clearance to participate, specifies in greater detail the restrictions on postemployment participation, establishes deadlines for the processing of clearance applications, and establishes a new procedure for firms to participate in Commission proceedings through screening of disqualified former employees.

DATE: These amendments are effective on June 26, 1981.

FOR FURTHER INFORMATION CONTACT: Barry R. Rubin, Assistant General Counsel, Federal Trade Commission, Washington, D.C. 20580, (202) 523-3520.

SUPPLEMENTARY INFORMATION: On August 4, 1978, the Commission published for comment (43 FR 35947) proposed revisions to § 4.1(b) of its Rules of Practice, 16 CFR 4.1(b), governing postemployment participation in Commission proceedings by former Commission members and employees. Subsequently, the Commission announced (44 FR 45179, Aug. 1, 1979) that it was deferring final action on this proposal until Congress decided whether further to amend the Ethics in Government Act and until the D.C. Court of Appeals acted on proposed "revolving door" amendments to Canon 9 of the Code of Professional Responsibility. The Ethics Act has been amended, and though the D.C. Court of Appeals has not taken final action, the Commission's final rule is compatible with the Court's previously announced proposed rule and further delay by the Commission appears to be unwarranted. The Commission is, therefore, now adopting a final rule. The Commission will reexamine its rule, as need be, after final action by the D.C. Court of Appeals.

The major elements of the revised rule are as follows: (1) The revised rule retains the basic procedure of its predecessor: If a former Commission member or employee (hereinafter "former employee") wishes to participate in a professional capacity in a Commission proceeding or investigation described in the rule, he or she must apply for permission to do so. However, the final rule differs from both the previous rule and the proposed rule in the details of this "clearance" mechanism. The old rule required filing if the proceeding or investigation was "pending in any manner," which commenters generally agreed was too vague a criterion. The proposed rule would have substituted a requirement for filing in all cases for a term of years after the end of an employee's tenure. However, the Commission believes that this approach is insufficiently linked to the substantive concerns that underlie the rule. Accordingly, the revised rule specifies the circumstances under which filing is required. These are the types of professional representation which, because of possible connections to the former employee's activities at the Commission, ought not to be undertaken without an agency determination that there is in fact no impropriety.

Advance permission must be obtained if the particular proceeding or investigation in which the former

employee wishes to participate was pending during the former employee's tenure, or if a directly antecedent investigation was pending. For example, if a former employee wishes to participate in an adjudication, he or she must seek clearance to do so if, during the former employee's tenure, an initial phase or formal investigation that directly led to the adjudication was pending. Filing is not required under this provision simply because some attenuated connection may be traced between a matter pending during the former employee's tenure and the current matter. Only if the very investigation or proceeding itself or a directly linked, earlier phase of the matter was pending must the former employee file.

A former employee who wishes to represent a party in an investigation of compliance with an order, to obtain reopening of an order, or to participate in an ongoing reopening proceeding, must also file for clearance if the former employee participated personally and substantially in the adjudicatory proceeding or its antecedent investigation (or, in the case of consent orders negotiated prior to complaint, the investigation) that resulted in the order in question.

These are situations in which there is sufficient potential for misuse of nonpublic information to warrant a clearance process. A last element of the new filing requirement touches another such situation. If a former employee "gained personal knowledge of nonpublic documents or information containing specific criteria for the initiation of future investigations or cases pertaining to a practice involved in the proceeding or investigation" in which the former employee wishes to participate, and if the participation is to occur within three years of the former employee's departure from the Commission, he or she must apply for clearance. This residual category is intended to reach instances in which knowledge of concrete enforcement plans may give rise to a present advantage. For example, while at the Commission, an attorney in the Bureau of Competition works on an enforcement protocol for vertical restraint cases in a particular market. This document suggests the kinds of cases to be emphasized and how they should be structured. After the attorney leaves the Commission, the Bureau opens an investigation into allegedly unlawful vertical restraints imposed by a company in that market. The attorney must apply for clearance to participate in that investigation.

Other examples, however, will suggest the limited scope of this residual requirement: An attorney works on a merger case involving a particular product market. After leaving the Commission, the attorney wishes to represent a company involved in a new Commission investigation of another merger in that market. Even though the attorney has been privy to nonpublic information about the Commission's view of the market, he or she need not file for clearance. Similarly, a former employee who attended a Commission budget meeting need not file under this provision, though such meetings often entail a general discussion of the types of investigations to be emphasized. A former employee who read memoranda reflecting the decisionmaking of a bureau's evaluation committee also need not file, though these decisions sometimes turn on whether a particular proposal fits within current enforcement priorities. None of these situations involves knowledge of "specific criteria for the initiation of future investigations or cases," within the meaning of the rule. The knowledge thus gained is too generalized to pose a risk of unfair advantage great enough to warrant the much broader filing requirement that would be necessary to capture all such cases for scrutiny. The three-year time limit for filing in situations covered by this provision is based upon a comparable recognition that, in reality, knowledge of even the most specific enforcement plan loses its special value rather rapidly. Of course, in any situation not covered by the rule, an attorney remains obliged under the Code of Professional Responsibility not to reveal the Commission's confidences and secrets or to use them to advantage of a private client. DR 4–101(B)(1), (3).

The Commission believes that this approach to the filing requirement provides greater clarity and predictability than the old rule. Former employees may seek the advice of the General Counsel if they are uncertain whether a clearance application is required in any given situation.

The phrase "appear as attorney or counsel or otherwise participate through any form of professional consultation or assistance" is meant to cover not only personal contacts with the agency but also office counseling and similar behind-the-scenes work. However, the requirement applies only to the kinds of proceedings or investigations delineated in the rule. That is, the rule does not apply to counseling or the like, unless the client is seeking advice about its involvement in a specific Commission proceeding or investigation. Commission employees quite naturally develop an expertise about the agency and its practice. The Commission would not wish to prohibit the diffusion of this knowledge (which is certainly shared by many who have never worked at the agency) even if it could. Its objective is simply to prevent lawyers and other professionals from gaining an unfair representational advantage from, and so trading on, nonpublic information. The filing of a clearance request prior to participating in a specific, ongoing matter permits this objective to be sought without hindrance to "preventive" lawyering and similar counseling.

(2) A former employee who seeks clearance must supply enough information to permit an informed decision on the request. This provision is largely unchanged from the prior rule.

(3) There are three bases on which a request for clearance would be denied. Two of them reflect prohibitions in the Ethics in Government Act. First, the former employee will be denied clearance if he or she participated personally and substantially in the proceeding or investigation for which clearance is sought. A request for clearance will also be denied if the clearance request is filed within two years after the former employee leaves the Commission and if, within one year prior to the termination of the former employee's service, he or she was officially responsible for the proceeding for which clearance to participate is sought. Finally, augmenting the statute with a restriction designed to eliminate the main potential cause of impropriety or the appearance of impropriety, the Commission will deny clearance if nonpublic documents or information, as denominated in § 4.10 of the Commission's rules, pertaining to the proceeding or investigation for which clearance is sought came to the attention, or would likely have come to the attention, of the former employee, unless the Commission finds that the nature of the documents or information is such that no present advantage could be derived from such "inside" information.

This standard is somewhat more specific than the test in the superseded rule, "actual or apparent impropriety." Still, the rule will gain practical meaning only in case-by-case application. That is inevitable. The Commission intends to examine, in each situation, the nature of the nonpublic information and its relation to the particular proceeding. Clearance would quite probably be denied, for example, to a lawyer who, a few months before, had read a

nonpublic enforcement strategy memo concerning a particular practice and now wants to represent a respondent in a proceeding where that strategy is being implemented. However, clearance might well be granted if the lawyer were applying two years after leaving the Commission, because intervening events might have rendered the information in the memo valueless in the intended representation. If information that once was nonpublic has been disclosed, or if information that remains nonpublic is nevertheless of little value in the particular matter, then clearance will not be denied on this basis.

(4) The rule also corporates the Ethics Act's restriction on postemployment appearances or communications, based not upon a former employee's contact with any particular matter, but rather derived from the kind of position held by the former employee. See 18 U.S.C. 207(c), (d). In order to allay public concern about the reappearance of former high-ranking public officials as private advocates, Congress and, by delegation, the Office of Government Ethics have identified the Commissioners and certain of the most senior staff members as appropriately subject to a flat ban against direct, personal efforts to influence the course of Commission decisionmaking during the year after their departure from the Commission.

(5) The General Counsel is delegated the authority to approve clearance requests. The Commission itself will issue any denial of a clearance request.

(6) In response to several comments, the Commission is establishing 15-day deadlines for the processing of clearance requests. One commenter proposed that the underlying proceeding or investigation be suspended during the pendency of a clearance request. While the Commission declines to adopt a rule provision to this effect, the Commission does expect its staff to accommodate, to the extent possible in light of particular law enforcement needs, any delay caused by processing of a clearance request.

(7) The rule itemizes several exceptions to which the various restrictions will not apply.

The exceptions listed in § 4.1(b)(7)(i) apply to all of the restrictions in the rule, while those listed in § 4.1(b)(7)(ii) apply to all but the one-year flat ban on appearances by former senior officials. Practitioners should note that the exception for Hart-Scott-Rodino filings, second requests, and related enforcement proceedings in § 4.1(b)(7)(ii)(C) does not extend to other activities that may be going on simultaneously. For example, if the Commission issues an investigational subpoena *ad testificandum* following a Hart-Scott-Rodino filing, clearance would be required for representational activity in connection with the subpoena. As a practical matter, therefore, the exception is meant to allow a former Commission attorney to represent a client in the initial phases of Hart-Scott-Rodino compliance without awaiting a clearance decision, but the attorney ought to file for clearance promptly, in case matters apart from Hart-Scott-Rodino compliance arise.

An exception applies to public record comments in a rulemaking, but other forms of participation in an ongoing rulemaking proceeding require clearance. The substantive tests of the rule likewise apply, though if the former employee had neither personally and substantially participated in the proceeding nor (during the prescribed period prior to departure) had been officially responsible for it, authorization will generally be given. Nonpublic information having some potential for conferring a present advantage is unlikely to arise frequently in rulemaking proceedings.

(8) A new procedure treats the question of participation by a firm when one of its members or associates is disqualified under the rule. For the reasons stated in Part II of our Order Denying Motion to Disqualify Counsel in *Brunswick Corporation*, Docket No. 9028 (Feb. 22, 1980), we adopt a procedure whereby a firm may participate in a matter, notwithstanding that one or more of the firm's members are disqualified on the basis of personal and substantial participation in the matter, if the firm establishes a satisfactory means of screening those who are disqualified from any involvement in the substance of the representation and from any of the fees resulting from it. The revised rule will require the filing of an affidavit attesting to these matters before the firm begins its participation. However, advance approval is not required and the firm may undertake its participation once it files the affidavit. The Commission reserves the right to terminate a firm's participation if it determines that the screening measures are inadequate or that improper solicitation by a disqualified former member or employee has occurred.

An affidavit is not a prerequisite to firm participation when one of the firm's members is unable to participate personally because of some reason *other* than personal and substantial prior participation. Requiring affidavits in these other circumstances would impose an undue burden on practitioners and the agency itself.

(9) In order to provide uniform treatment for all practitioners before this agency, regardless of the jurisdiction in which they are licensed, this rule is intended to apply in lieu of procedures imposed by other rules, such as disciplinary rules adopted by a jurisdiction's court of appeals, to the extent that such other procedures regulate when former Commission employees may participate in FTC proceedings or impose procedural requirements prior to such participation. Of course, all other ethical obligations required by the bars of which attorneys practicing before the Commission are members remain unaffected by this rule, and indeed they are incorporated by reference in paragraph (e)(1) of this section.

The Commission's intention with respect to ongoing representation is as follows:

(1) A former Commission member or employee who is properly participating in a Commission proceeding or investigation—that is, who obtained clearance under the prior rule or who was not required to obtain clearance under that rule—need *not* obtain clearance under the revised rule.

(2) Members or associates of a firm who are properly participating, notwithstanding the personal disqualification of a former Commission member or employee, pursuant to the restriction in prior § 4.1(b)(4) that the services of the former Commission member or employee not be utilized in any way, need *not* file the affidavit required by revised § 4.1(b)(8)(ii).

(3) However, if a former Commission member or employee joins a firm *after* the effective date of these amendments, and if that former member or employee is disqualified because of personal and substantial prior participation in a proceeding or investigation in which the firm is then participating, the firm must promptly file an affidavit in accordance with § 4.1(b)(8)(ii), to establish that the newly arrived member or associate of the firm is properly screened.

Accordingly, 16 CFR Part IV is amended by revising § 4.1(b) to read as follows:

§ 4.1 Appearances.

* * * * *

(b) *Restrictions as to former members and employees.* (1) Except as provided in this section or otherwise specifically authorized by the Commission, no former member or employee of the Commission shall appear as attorney or counsel or otherwise participate through

any form of professional consultation or assistance:

(i) in any proceeding or investigation, formal or informal, (A) if such proceeding or investigation was itself pending in the Commission while the former member or employee served with the Commission; (B) if an investigation from which such proceeding or investigation directly resulted was pending during such service; or (C) if such former member or employee, during the course of his service with the Commission, gained personal knowledge of nonpublic documents or information containing specific criteria for the initiation of future investigations or cases pertaining to a practice involved in the proceeding or investigation, and if the participation by the former member or employee would occur within three (3) years of the termination of his service with the Commission; or

(ii) in an investigation of compliance with an order, submission of a request to reopen an order, or a proceeding with respect to reopening of an order, if the former member or employee participated personally and substantially in the adjudicative proceeding or investigation that resulted in such order.

(2) In cases to which paragraph (b)(1) of this section is applicable, a former member or employee of the Commission may request authorization to appear or participate in a proceeding or investigation by filing with the Secretary of the Commission a written application therefor, disclosing the following information, to the extent known: (i) the nature and extent of the former member's or employee's participation in, knowledge of, and connection with the proceeding or investigation during his service with the Commission; (ii) in the case of applications filed pursuant to Paragraphs (b)(1)(i)(B), (b)(1)(ii), or (b)(1)(iii) of this section, the nature and extent of the former member's or employee's participation in, knowledge of, and connection with the predecessor investigation, adjudication or investigation, or rulemaking proceeding, respectively, during his service with the Commission; (iii) whether documents or information concerning the proceeding or investigation came to his attention and, if so, the nature of such documents or information; (iv) whether he was employed in the same bureau, office, division, or other administrative unit in which the proceeding or investigation is or has been pending; (v) whether he worked directly or in close association with Commission personnel assigned to the proceeding or investigation; and (vi) whether during his service with the commission he was engaged in any matter concerning the individual, company, industry, or any member of the industry involved in the proceeding or investigation.

(3) The requested authorization will not be given in any case (i) where it appears that the former member or employee during his service with the Commission participated personally and substantially in the proceeding or investigation; (ii) where the application is filed within two (2) years after termination of the former member's or employee's service with the Commission and it appears that within a period of one (1) year prior to the termination of his service the former member or employee was officially responsible for the proceeding or investigation; or (iii) where documents or information of the kind delineated in § 4.10(a) pertaining to the proceeding or investigation for which authorization is sought came to the attention of the former member or employee or would be likely to have come to his attention in the course of his duties, unless the Commission finds that the nature of the documents or information is such that no present advantage could thereby be derived.

(4) Notwithstanding any other provision of this section, no former member of the Commission and no former senior employee in a position designated by the Office of Government Ethics pursuant to 18 U.S.C. § 207(d) shall, for a period of one (1) year after termination of the former member's or employee's service in that position, appear as attorney or counsel or otherwise represent anyone (other than the United States) in any formal or informal appearance before the Commission in any proceeding or investigation or, with the intent to influence, make any oral or written communication on behalf of anyone in any proceeding or investigation which is before the Commission or in which the Commission has a direct and substantial interest.

(5) The General Counsel shall have the authority (i) to determine whether, under Paragraph (b)(1) of this section, a request for authorization to appear or participate need be filed and (ii) to grant any such request. In any case in which the General Counsel proposes that a request be denied, he shall refer the request to the Commission for determination, and in other unusual or difficult cases he may, in his sole discretion, refer a request to the Commission for determination.

(6) (i) The General Counsel shall (A) within three (3) working days of receipt of an oral or written request for a determination whether, under Paragraph (b)(1) of this section, a request for authorization to appear or participate need be filed, render such determination and (B) within fifteen (15) working days of the receipt of a request for authorization to appear or participate, either grant such request or refer it to the Commission.

(ii) The Commission shall, within fifteen (15) working days of the receipt of a request referred by the General Counsel pursuant to Paragraph (b)(5) of this section either grant or deny such request.

(iii)(A) The Commission or the General Counsel may, by written notice to the requester, and for good cause, extend the time limit for a determination by not more than fifteen (15) working days.

(B) Any time limit specified in this paragraph shall be tolled during such time as may elapse between a request by the Commission or General Counsel to the former member or employee for additional information and the receipt of such information by the Commission or General Counsel.

(7) (i) Paragraphs (b)(1), (b)(2), (b)(3) and (b)(4) of this section shall not apply to (A) pro se filings of any kind; (B) submissions of requests or appeals under the Freedom of Information Act, Privacy Act, or Government in the Sunshine Act; (C) testimony under oath; (D) submissions of statements required to be made under penalty of perjury; (E) submissions of statements based on the former member's or employee's own special knowledge in the particular area that is the subject of the statement, provided that no compensation is thereby received, other than that regularly provided by law or by § 4.5 for witnesses; and (F) appearances on behalf of the United States.

(ii) Paragraphs (b)(1), (b)(2), and (b)(3) shall not apply to (A) submissions of comments on a matter on which the Commission has invited public comment; and (B) filings of premerger notification forms or participation in subsequent events concerning compliance or noncompliance with Section 7A of the Clayton Act, 15 U.S.C. 18a, or any regulations issued pursuant to that section.

(8) (i) In any case in which a former member or employee of the Commission is prohibited under Paragraph (b)(3)(i) of this section from appearing or participating in a Commission proceeding or investigation, no partner or legal or business associate of such former member or employee shall appear or participate in such proceeding

or investigation, except as provided in this paragraph.

(ii) If a partner or legal or business associate of a former member or employee of the Commission prohibited under Paragraph (b)(3)(i) of this section from appearing or participating in a Commission proceeding or investigation wishes to appear or participate in such proceeding or investigation, he shall file with the Secretary of the Commission, not later than the time such appearance or participation begins, an affidavit attesting: (A) that the former member or employee will not participate in the proceeding or investigation in any way, directly or indirectly; (B) that he will not share, directly or indirectly, in any fees in the proceeding or investigation; (C) that all persons who intend to appear or participate are aware of the requirement that the former member or employee be screened from participating in or discussing the proceeding or investigation, or the firm's representation, and describing the procedures being taken to screen the personally disqualified former member or employee; (D) that the client or clients have been so informed; and (E) that the matter was not brought to such partner or legal or business associate through the active solicitation of the former member or employee.

(iii) Upon the filing of the affidavit, such partner or legal or business associate may begin such appearance or participation, *Provided, however,* That if the Commission finds (A) that the screening measures being taken are unsatisfactory or (B) that the matter was brought to such partner or legal or business associate through the active solicitation of the former member or employee, and so notifies such partner or legal or business associate, such appearance or representation shall cease immediately.

(9) (i) The restrictions and procedures in this subsection are intended to apply in lieu of restrictions and procedures as may be adopted by the appropriate authority in any state or jurisdiction, insofar as such restrictions and procedures apply to appearances or participation in Commission proceedings or investigations, *Provided, however,* That nothing in this section supersedes other standards of ethical conduct required under paragraph (e) of this section.

(ii) In the event that Commission approval is sought for an appearance or participation by a former member or employee in a proceeding in court or before another agency, the General Counsel shall have the authority to respond to such a request, applying as appropriate the standards of this subsection.

(15 U.S.C. 46(g))

By direction of the Commission.

Carol M. Thomas,

Secretary.

[FR Doc. 81-14201 Filed 5-11-81; 8:45 am]

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Human Prescription Drugs in Oral Dosage Forms; Exemption of Pancrelipase Preparations in Tablet, Capsule, or Powder Form From Child-Protection Packaging Requirements

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Commission exempts pancrelipase preparations in tablet, capsule, or powder form from child-protection packaging requirements. Pancrelipase provides additional pancreatic enzymes, and is particularly used in the treatment of children with cystic fibrosis. The information available to the Commission indicates that child-protection packaging for this drug is not needed to protect children from serious illness or injury, because of the low toxicity of pancrelipase and lack of adverse human experience associated with the drug. This exemption is in response to a petition from Johnson & Johnson Baby Products Company, a manufacturer of a capsule form of pancrelipase.

DATE: This exemption is effective May 12, 1981.

FOR FURTHER INFORMATION CONTACT: Charles Jacobson, Directorate for Compliance and Administrative Litigation, Consumer Product Safety Commission, Washington, D.C., 20207, telephone (301) 492-6400.

SUPPLEMENTARY INFORMATION:

Background

On April 26, 1979, the Commission received a petition (PP 79-3) from Johnson & Johnson Baby Products Company, of Raritan, N.J., requesting an exemption from child-protection (special) packaging requirements for pancrelipase in 100 and 250 capsule containers. A large amount of the drug is regularly used as replacement therapy for pancreatic enzyme insufficiency in children with cystic fibrosis. Such children may be taught to self-administer the drug at an early age (5-8 years) because the medication must be taken at all meals and snacks.

Grounds for Exemption

The petitioner stated that an exemption for pancrelipase is justified based upon the low toxicity of the drug as shown by the lack of adverse human experience data. Data from the National Clearinghouse for Poison Control Centers (NCPCC) indicate that only two ingestions of pancrelipase products were reported during the period from 1969 through 1978. These two ingestions occurred in 1974, and no symptoms or hospitalization were involved in either case. In addition, a medical literature search back to 1950 does not reveal any articles on the accidental ingestion of pancrelipase. Physicians' reports included in the petitioner's supporting material reveal that no adverse reactions occurred in patients taking the petitioner's pancrelipase preparation during clinical studies. Also, animal toxicity studies could not determine the Median Lethal Dosage of pancrelipase in rats and mice, as doses up to 9.336 grams per kilogram did not produce death in any of the animals tested. Another study cited by the petitioner demonstrates that the single dose ingestion of an entire container of 250 capsules by each of four beagle dogs did not produce any toxic effects.

An examination of the most current data sources available to the Commission staff reveals no reports of pancrelipase ingestion other than the two reports in 1974 (neither involving symptoms or hospitalization) which are cited in the petition and referenced above. The staff examined the data supplied by the petitioner, statistics from the National Clearinghouse for Poison Control Centers for the period 1969 through 1978, data from the National Electronic Injury Surveillance System for 1978, 1979, and 1980, accident investigation reports, and the Commission's consumer complaint, injury and potential injury, and death certificate files.

Johnson & Johnson also argued that an exemption for pancrelipase is justified because special packaging could adversely affect the utility and stability of the drug. According to the petitioner, because the cystic fibrotic children who need access to the drug care not physically strong, opening the child-resistant closure is especially difficult, and special packaging could interfere with self-administration of the medication. In addition, the petitioner argued that if such difficulty causes the children to leave the closure loosened, then the capsules would be exposed to