

§95.6029 VOR FEDERAL AIRWAY 29

is amended to read in part:

FROM	TO	MEA
Modena, Pa. VOR	Pottstown, Pa. VOR	2400

§95.6047 VOR FEDERAL AIRWAY 47

is amended to delete:

FROM	TO	MEA
Waterville, Ohio VOR	Milan INT, Mich.	2400
Milan INT, Mich.	Salem, Mich. VOR	2600
Salem, Mich. VOR	Hunter INT, Mich.	2800

§95.6071 VOR FEDERAL AIRWAY 71

is amended to read in part:

FROM	TO	MEA
Bismark, N. D. VOR	Pippy DME Fix, N. D.	
	W-bound	5600
	E-bound	3400
Pippy DME Fix, N. D.	Williston, N. D. VOR	*5600

*3800-MOCA

§95.6140 VOR FEDERAL AIRWAY 140

is amended to read in part:

FROM	TO	MEA
Tulsa, Okla. VOR	Adair INT, Okla.	
Via N alter.	Via N alter.	2500

§95.6161 VOR FEDERAL AIRWAY 161

is amended to read in part:

FROM	TO	MEA
Ardmore, Okla. VOR	Phard INT, Okla.	3000

§95.6163 VOR FEDERAL AIRWAY 163

is amended to delete:

FROM	TO	MEA
Madre INT, Tex	Raymo INT, Tex	
Via W alter	Via W alter	1600
Raymo INT, Tex.	Jetty INT, Tex	
Via W alter	Via W alter	*4000

*1300 - MOCA

§95.6169 VOR FEDERAL AIRWAY 169

is amended to read in part:

FROM	TO	MEA
Solen DME Fix, N. D.	Bismarck, N. D. VOR	
	S-bound	4700
	N-bound	4400

§95.6190 VOR FEDERAL AIRWAY 190

is amended to read in part:

FROM	TO	MEA
*Acoma INT, N. M.	**Albuquerque, N. M. VOR	***9000
	*11500-MCA Acoma, SW-bound	
	**11500-MCA Albuquerque, NE-bound	
	***8400-MOCA	

§95.6194 VOR FEDERAL AIRWAY 194

is amended to read in part:

FROM	TO	MEA
Tar River, N. C. VOR	Cotfield, N. C. VOR	1800

§95.6210 VOR FEDERAL AIRWAY 210

is amended to read in part:

FROM	TO	MEA
Bucks INT, Pa.	Propp INT, Pa.	3000

§95.6212 VOR FEDERAL AIRWAY 212

is amended by adding:

FROM	TO	MEA
Alexandria, La. VOR	Larto INT, La.	
Via N alter.	Via N alter.	1900
Larto INT, La.	Natchez, Miss. VOR	
Via N alter.	Via N alter.	2000
Natchez, Miss. VOR	Mc Comb, Miss. VOR	
Via N alter.	Via N alter.	2000

§95.6297 VOR FEDERAL AIRWAY 297

is amended to delete:

FROM	TO	MEA
Carleton, Mich. VOR	Livingston INT, Mich.	2900
Livingston INT, Mich.	Owosso INT, Mich.	*4000
*2600-MOCA		
Owosso INT, Mich.	Saginaw, Mich. VOR	2600

§95.6358 VOR FEDERAL AIRWAY 358

is amended to read in part:

FROM	TO	MEA
San Antonio, Tex. VOR	*Guada INT, Tex.	4000
*4300-MRA		

§95.6377 VOR FEDERAL AIRWAY 377

is amended by adding:

FROM	TO	MEA
Montebello, Va. VOR	Kessel, W. Va. VOR	6000

§95.6405 HAWAII VOR FEDERAL AIRWAY 5

is amended to read in part:

FROM	TO	MEA
Maona INT, Hawaii	*Rowin INT, Hawaii	
Via W alter.	Via W alter.	**4000
	*7500-MCA Rowin INT, N-bound	
	**2800-MOCA	

§95.6407 HAWAII VOR FEDERAL AIRWAY 7

is amended by adding:

FROM	TO	MEA
Joele INT, Hawaii	INT 347 M rad Molokai	4000
	VOR/90 NM	
INT 347 M rad Molokai	INT 347 M rad Molokai	7000
VOR/90 NM	VOR/140 NM	
INT 347 M rad Molokai	Zigie DME Fix, Hawaii	22000
VOR 140 NM		

§95.6417 HAWAII VOR FEDERAL AIRWAY 17

is amended by adding:

FROM	TO	MEA
Stait INT, Hawaii	Fredi INT, Hawaii	17000
Fredi INT, Hawaii	Rexie INT, Hawaii	22000

§95.6484 VOR FEDERAL AIRWAY 484

is amended to read in part:

FROM	TO	MEA
Woden INT, Ida.	*Dryad INT, Utah	**12000
	*13000-MCA Dryad, SE-bound	
	**10100-MOCA	

§95.6493 VOR FEDERAL AIRWAY 493

is amended to delete:

FROM	TO	MEA
Carleton, Mich. VOR	Livingston INT, Mich.	*3000
*2300-MOCA		
Livingston INT, Mich.	Owosso INT, Mich.	*4000
*2100-MOCA		
Owosso INT, Mich.	Mt. Pleasant, Mich. VOR	3000

14 CFR Part 121

[Docket No. 19652; Amdt. No. 121-156]

Petition for Rulemaking—Carriage of Weapons; Military Charter Flights**AGENCY:** Federal Aviation Administration (FAA), DOT.**ACTION:** Final rule.

SUMMARY: The purpose of this amendment is to remove any prohibition against the carriage of weapons by military personnel aboard aircraft under charter or contract to the Department of Defense (DOD) or its component military departments and to clarify the requirements applicable to carriage of firearms in checked baggage aboard aircraft. The amendment pertaining to military personnel results from a petition for rule making submitted by the DOD. These amendments are necessary to provide for safety in air commerce.

EFFECTIVE DATE: March 31, 1980.**COMMENTS DUE:** May 28, 1980.

FOR FURTHER INFORMATION CONTACT: Mr. Eli Newberger, Regulatory Projects Branch (AVS-24), Federal Aviation Administration, 800 Independence Avenue, S.W., Washington, D.C. 20591; telephone (202) 755-8716.

ADDRESS: Comments on this amendment may be mailed in duplicate to:

Federal Aviation Administration, Office of the Chief Counsel, Attn: Rules Docket (AGC-24), Docket No. 19652, 800 Independence Avenue, S.W., Washington, D.C. 20591;

or be delivered in duplicate to:
Room 916, 800 Independence Avenue, S.W., Washington, D.C. 20591.

Comments delivered must be marked "Docket No. 19652".

Comments may be inspected at Room 916 between 8:30 a.m. and 5:00 p.m.

Discussion

Currently, § 121.585 only permits certain persons to carry weapons aboard U.S. domestic, flag, and charter (supplemental) air carriers and intrastate air carrier flights when these persons have a need to have such weapons during flight (such as a law enforcement officer escorting a dangerous prisoner).

On August 28, 1979, Department of Defense (DOD) petitioned the agency to amend § 121.585 of the Federal Aviation Regulations to remove the prohibition against the carriage of weapons by military personnel aboard aircraft under charter or contract to DOD or its component military departments.

In accordance with FAA rulemaking procedures (14 CFR Part 11), a summary of this petition was published in the Federal Register (44 FR 61376; October 25, 1979), to improve the public awareness of this aspect of FAA's regulatory activities. Closing date for comments on the petition was December 24, 1979. No comments were received.

As a result of experience gained over the years during training exercises, DOD states that they have become concerned about the adequacy of methods employed to air transport individual carry-on weapons aboard civil aircraft under contract or charter flights. Present acceptable methods are to carry weapons assembled in containerized compartments in the baggage hold area(s) or render the weapon inoperable by having the bolts removed and securely stored in baggage compartments not accessible during flight.

Use of these methods has revealed that in an actual contingency situation during peacetime, when no national emergency has been declared, the time required to pack or disassemble the weapons at origin for movement and to distribute or make them operational at destination may be excessive. Matching of bolts with original weapons is extremely time consuming but essential to avoid possible damage to the mechanism or injury to personnel. These factors extend response time and consequently impede the effectiveness of contingency operations and training exercises designed to test unit readiness. DOD further stated that these exercises should simulate as closely as possible deployment under actual emergency conditions.

DOD advises that the Military Airlift Command routinely transports military personnel with operable weapons aboard its aircraft and that during 1979, approximately 4,000 flights were completed and during its long history of this practice, no injury to personnel or damage to aircraft has resulted.

The restriction imposed on the carriage of weapons aboard air carrier flights were part of the agency's program to counter the increased threat of hijacking. These security measures were primarily aimed at individually ticketed passengers. In promulgating these standards, the agency was not concerned with planeloads of military troop movements airlifted by civil aircraft. However, the prohibitions contained in § 121.585 prevent military personnel from carrying weapons on chartered flights.

Amendment of the regulation to permit carriage of weapons by military personnel on chartered flights under

limited conditions would be in the public interest and will not adversely affect safety. Weapons may only be carried aboard flights in which the cabin load of the aircraft is under exclusive use of military forces of the United States Government. A precaution is added that unit commanders or officers in charge of the air movements shall notify the certificate holder prior to the boarding and that all weapons taken aboard are not loaded and that all bolts to firearms are locked in the open position. In situations in which representatives of the certificate holder are not available, notification may be made to the pilot.

In addition to addressing the matters presented by DOD, this amendment clarifies the intent of § 121.585(b). It has always been the intent of § 121.585 that a firearm is considered loaded if ammunition is in a magazine, clip, or cylinder attached to the weapon. There are apparently some members of the public who do not interpret "loaded" to include ammunition in a magazine or clip inserted into the weapon.

Accordingly, to ensure that the intent of § 121.585(b) is clear, it is amended to include a definition of "loaded."

Need For Immediate Adoption

Since these amendments are only clarifying in nature and establish provisions necessary for the DOD to support contingency operations and are in the national interest, the FAA has concluded that good cause exists for this amendment and that notice and public procedure are unnecessary and contrary to the public interest and that these amendments may be made effective without notice. However, interested persons are invited to submit such comments as they may desire regarding this amendment. Communications should identify the docket number and shall be submitted in duplicate to the address specified above. All communications received on or before the date for comments specified above will be considered by the Administrator and the amendment may be changed in light of the comments received. All comments received will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this invitation to comment, shall submit with those comments, a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 19652". The postcard will be date/time stamped and returned to the commenter.

Adoption of the Amendment

Accordingly, § 121.585 (14 CFR 121.585) is amended effective March 31, 1980 by amending paragraph (b) by adding a new sentence and by adding a new paragraph (e) to read as follows:

§ 121.585 Carriage of weapons.

(b) * * * For the purpose of this section, a loaded firearm means a firearm which has a live round of ammunition, cartridge, detonator or powder in the chamber or in a clip, magazine, or cylinder inserted in such firearm.

(e) Except for paragraphs (b) and (d), § 121.585 does not apply to the carriage of weapons aboard air carrier flights conducted for the military forces of the Government of the United States when the total cabin load of the airplane is under exclusive use by those military forces if the following conditions are met:

(1) No firearm is loaded and all bolts to such firearms are locked in the open position; and

(2) The certificate holder is notified by the unit commander or officer in charge of the charter prior to boarding that weapons will be carried aboard the aircraft.

(Secs. 313(a), 316, 601, 1005, Federal Aviation Act of 1958 (49 U.S.C. 1354(a), 1357, 1421, and 1485); and Sec. 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)))

Note.—The FAA has determined that this document involves a regulation which is not significant under Executive Order 12044, as implemented by DOT Regulatory Policies and Procedures (14 FR 11034; February 26, 1979), and that, since it is clarifying in nature and imposes no additional burden on any person, the anticipated impact is so minimal that an evaluation is not required.

Issued in Washington, D.C. on February 20, 1980.

Langhorne Bond,
Administrator.

[FR Doc. 80-5826 Filed 2-27-80; 8:45 am]

BILLING CODE 4910-13-M

FEDERAL TRADE COMMISSION**16 CFR Part 13**

[Docket No. C-3007; Correction]

Bayer Ag, et al.; Prohibited Trade Practices, and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Correction.

SUMMARY: The Summary Statement published in FR Doc. 80-4686, February

14, 1980 misstated the full requirements of the divestiture order described therein. This document sets forth the correct version of the Summary Statement in the Matter of Bayer AG, et al., FTC Docket No. C-3007.

DATES: Effective February 28, 1980.

FOR FURTHER INFORMATION CONTACT: Gregory E. Hales, SSR-I-514, Federal Trade Commission, 6th Street and Pennsylvania Avenue, N.W., Washington, D.C. 20580. (202) 724-1185.

SUPPLEMENTARY INFORMATION: On Thursday, February 14, 1980, there was published in FR Doc. 80-4686, 45 FR 9894, a Final Order in the Matter of Bayer AG, et al. The summary statement to that document incorrectly stated one of the provisions of the final order.

The summary statement is revised to read as follows:

"In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent order, among other things, requires a diversified chemical company, located in Leverkusen, Germany, and its two American subsidiaries to divest within one year to a Commission-approved buyer, all United States assets gained through their acquisition of Miles Laboratories, Inc., primarily utilized in the manufacture, distribution or sale in the United States of allergenic extracts. Additionally, for specified time periods, the firms would be barred from acquiring, without prior Commission approval, any concern engaged in the manufacture, distribution or sale in the United States of allergenic extracts or chemically treated diagnostic reagent strips used for *in vitro* quantitative urinalysis.

Carol M. Thomas,
Secretary.

[FR Doc. 80-6466 Filed 2-27-80; 8:45 am]

BILLING CODE 6750-01-M

CONSUMER PRODUCT SAFETY COMMISSION**16 CFR Part 1702****Petitions for Exemptions From Poison Prevention Packaging Act Requirements; Petition Procedures and Requirements**

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule; withdrawal of interim rule.

SUMMARY: In this document, the Commission issues procedures for petitioning the Commission to grant exemptions from child-protection

packaging standards under the Poison Prevention Packaging Act of 1970. This document also establishes requirements and recommendations for the types of information to be supplied with the petitions to enable the Commission to properly evaluate and decide on exemption requests. The document also withdraws regulations that the Commission issued on an interim basis concerning these petitions.

DATES: The regulation is effective for petitions for exemptions received after March 31, 1980. The Commission will consider petitions received before this date under the present interim regulations for petitions.

FOR FURTHER INFORMATION CONTACT: Dr. Fred Marozzi, Division of Safety Packaging and Scientific Coordination (301) 492-6447, Consumer Product Safety Commission, Washington, D.C. 20207.

SUPPLEMENTARY INFORMATION:**A. Background**

Section 3(a) of the Poison Prevention Packaging Act (PPPA) authorizes the Consumer Product Safety Commission to establish standards for the special (child-resistant) packaging of household substances. Special packaging standards that have been issued appear at 16 CFR 1700.15. The Commission regulations at 16 CFR 1700.14 name particular substances or categories of substances that must comply with these standards by being packaged in special packaging.

Under the PPPA, the Commission has authority to grant exemptions from special packaging standards. Congress anticipated that in appropriate circumstances the regulations establishing special packaging requirements could be amended to exclude a single substance or category of substances. The granting of exemptions from special packaging was contemplated in the *Conference Report* of the Poison Prevention Packaging Act of 1970 (H.R. Rep. No. 1755, 91st Cong., 2d Sess. 8 (1970)).

After evaluating the information submitted by the petitioner and other available information, the Commission either grants or denies the petition. If the petition is granted, the Commission publishes a notice of proposed rulemaking inviting public comment on whether the exemption should be issued in final form.

In the September 7, 1977 *Federal Register* the Commission published, and solicited comments on, an interim rule containing procedures and requirements for petitions for exemptions from special packaging standards under the PPPA (42 FR 44802). The interim rule has been in effect to provide guidance for petitions

since August 7, 1977. Before the interim rule was issued the Commission accepted petitions for exemptions and used the basic factors for evaluating petitions stated in the preamble of the regulation establishing special packaging standards for oral prescription drugs (38 FR 9431 at 9432, April 16, 1973). The preamble to the oral prescription drug regulation states that petition requests "must furnish reasonable grounds therefor, including information such as available human experience data, relevant experimental data, toxicity information, product and packaging specifications, labeling, marketing history, and the justification for the exemption." As in the case of the interim regulation, the regulation issued below expands this basic statement and specifies, with as much detail as possible, the types of information the Commission considers necessary to evaluate petitions for exemption.

These grounds, and the requirements set forth below, generally are based on the statutory findings the Commission must make to establish a standard for a particular substance or category of substances. Section 3 of the PPPA provides for the establishment of standards requiring special packaging for a household substance if the Commission finds that:

(1) The degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance; and

(2) The special packaging to be required by such standard is technically feasible, practicable, and appropriate for such substance.

Before establishing a standard, the Commission must consider:

(1) The reasonableness of such standard;

(2) Available scientific, medical, and engineering data concerning special packaging and concerning childhood accidental ingestions, illness, and injury caused by household substances;

(3) The manufacturing practices of industries affected by the Act, and

(4) The nature and use of the household substance.

The type of information specified in this regulation is similar to the relevant information the Commission is required to consider in establishing special packaging standards for a particular household substance or category of substances. The information specified in this regulation is also generally necessary in order for the Commission to determine that the degree or nature of

the hazard to children is such that special packaging is not required to protect children from serious personal injury or serious illness, or that special packaging required for a household substance is not technically feasible, practicable, or appropriate.

B. Summary of Regulations

The regulation issued in this document, at § 1702.2, sets forth procedural requirements that must be met before the Commission will accept a petition for filing. These procedural requirements and recommendations are similar to those contained in the Commission's Interim Procedures for Petitioning for Rulemaking under section 10 of the Consumer Product Safety Act, 16 CFR 1110.7 (41 FR 43128, September 29, 1976).

At § 1702.3(a), the regulation sets out substantive requirements that must be met before the Commission will consider the merits of a petition. If a petition does not contain the required information, or an explanation as to why it is lacking, the petition will be closed unless the petitioner, upon notification by the Commission, is able to furnish the information or provide a satisfactory explanation for the absence of the information, as provided by § 1702.4. Section 1702.3(b) defines "reasonably available" information as data that is in the petitioner's possession, data that has been previously generated by the petitioner, and data that is obtainable from such sources as reports from Poison Control Centers; reports of adverse reactions that have been submitted to the petitioner; the medical, pharmacological and toxicological literature; and information required by FDA for an Investigational Exemption for a New Drug (IND) or a New Drug Application (NDA).

Section 1702.5 provides that the failure to supply reasonably available information that is unfavorable to the petition will result in the denial of the petition.

The regulation, at § 1702.6, provides for treatment of trade secrets and other confidential information in petitions in accordance with the Commission's regulations under the Freedom of Information Act.

In order to be considered complete, the petition must contain a statement of justification for the exemption in accordance with § 1702.7; and must include all reasonably available information concerning human experience data; reasonably available relevant experimental data (both human and animal); product and packaging specifications; labeling; and marketing

history; in accordance with §§ 1702.8 through 1702.14.

Section 1702.8 requires petitions to include all reasonably available human experience data involving all adverse reports of personal injury, illness, and significant allergenicity. Such information in children is of particular importance in evaluating exemption requests. However, similar data in adults must also be submitted if available. Human experience data may be obtained from reports of poison control centers; reports of adverse reactions concerning the product submitted to the company by physicians, hospitals, consumers, and other sources; extensive searches of the medical, pharmacological, and toxicological literature; and, for drugs, a summary of relevant human experience data required to be compiled for an Investigational Exemption for a New Drug (IND) or a New Drug Application (NDA).

Section 1702.9 specifies the requirements and recommendations for relevant experimental data to be submitted with petitions. Subsection 1702.9(a) lists minimum acute animal toxicity data that must be submitted with petitions, if reasonably available; § 1702.9(b) lists additional data that must be submitted for drug products and all other household substances which are normally intended to be used in or on the human body, if reasonably available. Subsection 1702.9(c) lists the additional data that should be submitted by petitioners, if reasonably available, for substances not intended for use in or on humans or animals.

At § 1702.9, concerning relevant experimental data, the Commission has changed from mandatory to suggested, the language in the proposal describing the quality of relevant experimental data to be submitted with petitions. These changes were made to clarify that existing relevant experimental data must be submitted, if reasonably available, even if the data do not strictly meet all of the qualitative criteria of this section. The Commission believes that such data can still be relevant to a decision to grant or deny the petition and should not be excluded even if the data are not in strict conformance with the qualitative provisions. However, where the petitioner decides to conduct new experimental studies, such studies should be designed to meet the qualitative provisions of this section.

At § 1702.9(b)(2), the Commission has also changed the language in the proposal discussing the role of the medical and scientific literature in granting exemptions. The revised language makes it clear that petitioners

must submit an evaluation of the pharmacology and toxicology of the substance based on reasonably available medical and scientific literature. The revised language also makes it clear that when considering requests for exemptions based on the medical and scientific literature, the Commission will, to the extent possible, evaluate such requests under the criteria specified in § 1702.9(a) for the submission of laboratory data. In addition, the revised language makes it clear that in certain cases where the laboratory data specified by § 1702.9 (a) and (b) are unavailable, the medical and scientific literature may justify granting an exemption, especially where the pharmacology and toxicology of the substance is well documented in the literature.

Section 1702.10 provides that any human experimental data submitted with a petition must indicate that adequate measures have been taken to safeguard the subjects of the studies from psychological or physical injury.

The Commission's technical staff will in each instance determine whether submitted data are sufficient and appropriate in order for the Commission to evaluate the merits of petitions.

Section 1702.11 of the regulation outlines product specifications that must be included in each petition for an exemption. Section 1702.12 provides packaging specifications that must be included in each petition for an exemption. Section 1702.13 requires petitions to include sample labeling and any package inserts, as well as samples of the promotional information or advertising, in the case of drugs. Section 1702.14 provides that petitions must include a statement of the marketing history of the substance.

The regulation, at § 1702.15, requires petitions alleging the incompatibility of child-resistant packaging with the substance petitioned for exemption to contain adequate evidence supporting the allegation. Section 1702.16 of the proposed regulation specifies requirements for petitions requesting an exemption for a drug or a new drug.

Section 1702.17 provides that where the Commission determines that reasonable grounds for an exemption are presented by a petition, the Commission shall publish a proposed exemption in the *Federal Register*. "Reasonable grounds" for publishing a proposed exemption may be based on information and data sufficient to support the conclusion that the degree or nature of the hazard to children in the availability of the substance, by reason of its packaging, is such that child-resistant packaging is not required to

protect children from serious personal injury or serious illness resulting from handling, using, or ingesting the substance. Reasonable grounds may also be present where information and data support the conclusion that special packaging is not technically feasible, practicable, or appropriate for the substance; or that special packaging is incompatible with the particular substance. Section 1702.18 provides that where the Commission determines that reasonable grounds for an exemption are not presented by the petition, the petition will be denied.

As provided by § 1702.19, the filing of a petition does not have the effect of automatically staying the regulation from which the exemption is sought. Even though a petition for an exemption has been filed, substances subject to child-resistant packaging standards are considered in violation of the law unless packaged in child-resistant packaging.

C. Response to Comments Received on the Interim Regulations

In response to the interim regulations, the Commission received seven comments from manufacturers, trade associations, and a government agency. These comments are available for inspection in the Office of the Secretary of the Commission. An explanation of the relevant issues raised by the comments, along with the Commission's response, is given below:

Human Experience Data (1) (§ 1702.8, § 1702.16(a))

One commentator questioned the requirement, at §§ 1702.8 and 1702.16(a) that petitions include adverse reaction reports filed under the FDA's Adverse Reporting Program. According to the commentator, much of this information would not be relevant to whether a product should be exempted from the requirement of special packaging.

Since human experience data are often scarce, especially concerning acute ingestions, the Commission believes that it is necessary to examine all available human experience data in order to decide whether a substance should be exempt from the requirement of special packaging. As a result, the Commission believes that all adverse reaction reports filed with the FDA should be submitted with the petition.

Another commenter stated that § 1702.8(b) should be changed to allow the petitioner to submit reports of adverse reactions associated with the ingredients of products.

Under the regulations a petitioner may submit reports of adverse reactions associated with ingredients of a product, in addition to reports of adverse

reactions concerning the product itself. However, a combination of ingredients may have different chemical and physiological properties than the individual components. As a result, toxic reactions to a product may in some cases differ considerably from toxic reactions to the ingredients of a product. For this reason, the regulation requires petitions to include reasonably available adverse reaction reports concerning the actual product for which the exemption is requested.

The same commentator also requested that § 1702.8 be changed to allow petitioners to include relevant human experience data for closely related products, such as products that utilize equivalent dosage forms, that contain similar ingredients or have similar physical characteristics. According to the commentator, human experience data for new products are often unavailable since the product has either not been marketed for a long time, or has been marketed in complying packaging.

The regulations do not preclude petitioners from submitting relevant human experience data for products that are closely related to the substance that is the subject of the petition. The Commission realizes that in certain instances physical characteristics of related products, e.g., effervescence, may be appropriate and relevant to evaluating petitions, even though the ingredients of the related products are not the same as the product that is the subject of the petition. However, where relevant human experience is reasonably available for the substance that is the subject of the petition, this data must be submitted with the petition as required by §§ 1702.3(a) and 1702.8(a). The Commission agrees with the commentator that specific human experience data may be unavailable for some new products. In order to help address this situation the Commission has added language to § 1702.8 that requires petitioners to submit reasonably available human experience data for generic equivalents of the product. A generic equivalent of the product would have the same dosage form and the same ingredients as the product that is the subject of the petition.

(2) Relevant Experimental Data (§ 1702.9)

One commentator suggested that § 1702.9 be reworded to require petitions to include only experimental data concerning hazards that the PPPA is intended to prevent. According to the commentator, some experimental data for some drug products concerns hazards, such as risks from long term exposure or

risks to women during pregnancy, that do not affect children under five and thus are not relevant in deciding whether to exempt a product from special packaging requirements.

Section 1702.9(a) describes the types of hazards most frequently associated with the handling or use of household products by children. Although the risk of injury from acute accidental ingestion is the hazard most frequently associated with young children, other hazards may exist for certain products, such as the potential for significant allergenicity, or dermal or ophthalmic injury. If these hazards exist, the petition must include data evaluating the nature and degree of these additional hazards. However, the Commission agrees with the commentor that data concerning hazards associated with the long term use of some drugs, and data concerning the danger to women during pregnancy would generally not be relevant to processing petitions under the PPPA and would not have to be included in the petition for an exemption.

One commentor questioned the advisability of requiring petitions regarding over-the-counter (OTC) drugs to include the relevant experimental data specified in §§ 1702.9(a) and 1702.9(b). The commentor stated that since the FDA's OTC Advisory Review Panels are currently evaluating the safety and efficacy of OTC drug products, the information at § 1702.9 would be duplicative of the information in the final reports issued by the FDA's OTC Review Panels. The petitioner suggested that the information required by § 1702.9 be waived where a final report has been issued by the FDA's OTC Review Panels for the OTC product that is the subject of the PPPA petition.

The FDA panels are reviewing and evaluating the pharmacology and toxicology of OTC products in terms of their safety, efficacy, and labeling for use by the consumer under normal circumstances. The FDA panels are not reviewing these drugs for safety in the acute overdosage situation which is of major importance in deciding whether a PPPA exemption should be granted for a particular drug. Since the type of experimental data concerning the safety of products in acute overdosage situations may often be different from the data for safety under normal circumstances, the Commission believes that petitions to exempt OTC products must include, to the extent reasonably available, the information specified at § 1702.9.

Several commentors recommended that median lethal dose (LD 50) determinations and statistical analysis

of LD 50 data should not be required for all petitions, but instead confined to those situations where the data are relevant and appropriate. The commentor stated that the development of these data is expensive and should be confined to situations that will benefit the public.

The Commission believes that LD 50 determinations are a fundamental, though not complete, indicator of a substance's toxicological profile. Generally, LD 50 determinations are among the least costly of the various toxicological studies that may be performed on a substance. However, where the petitioner believes that LD 50 determinations are not necessary for a toxicological evaluation of the product, the petitioner may omit such data and justify its absence, as provided in § 1702.4.

Several commentors recommended that the Commission eliminate the description at § 1702.9(a)(2) of minimum provisions for performing animal studies in support of exemption requests. The commentors stated that since the FDA and EPA are currently developing Good Laboratory Practices (GLP) procedures, the procedures in the Commission's regulation could be inconsistent with the procedures of other agencies. The commentors suggested that the regulation reference the final FDA/EPA procedures. One of the commentors suggested that the provisions at § 1702.9(a)(6) concerning test animals in acute toxicity studies be issued as a guideline rather than as part of a regulation in order to achieve additional flexibility.

The provisions at § 1702.9(a)(2) concerning procedures for conducting animal studies are not comprehensive good laboratory practice procedures, such as those to be issued by the FDA and EPA, but are a description of the quality of data that should be submitted with petitions for an exemption. The Commission does not anticipate any conflict between the provisions at § 1702.9(a)(2) and the GLP regulations to be issued by FDA and EPA. The Commission believes that the provisions at § 1702.9(a)(6) concerning test animals in acute toxicity studies are flexible and should be issued as part of the regulation. As explained earlier, the Commission has revised the language in section 1702.9 to clarify that existing relevant experimental data must be submitted, if reasonably available, even if the data do not strictly meet all of the qualitative criteria of this section.

(3) *Packaging Specifications, Labeling Requirements, and Marketing History* (§ 1702.12, 1702.13, 1702.14)

One commentor stated that §§ 1702.12 and 1702.13 of the regulations, which require manufacturers or packers of a substance requiring special packaging to provide the Commission with a sample of the packaging and labeling for the substance, are duplicative of § 1700.14(b) of the Commission's regulations. Section 1700.14(b) requires manufacturers or packers of substances requiring special packaging to provide the Commission with a sample of each type of special packaging and a sample of the label for each product. The Commission agrees with the commentor and, as suggested by the commentor, has changed §§ 1702.12 and 1702.13 to state that petitions for an exemption must include packaging specifications and labeling for the particular form(s) of the product for which an exemption is sought rather than samples of all forms of the product. The purpose of this provision is to ensure that the Commission has a current sample of the packaging and labeling for the substance that is covered by the petition. The Commission has also eliminated a duplicative provision concerning the description of the package size at § 1702.2(a)(7).

One commentor questioned the requirement at § 1702.13 that petitions to exempt drugs include complete promotional information or advertising. According to the commentor, this information has no bearing on a PPPA exemption and is needlessly burdensome on manufacturers who heavily promote products such as OTC drugs. The commentor stated that since OTC advertising and promotional materials are voluminous and subject to constant change, petitioners would have to submit substantial amounts of documents and would have to continually update this information by submitting new documents.

The Commission believes that advertising and promotional information is a valuable source of information concerning the various uses of the product and indicates the amount of drug that might be expected to be found in the home at any one time. However, the Commission agrees with the commentor that it is not necessary to submit all such information. The Commission believes that samples of promotional and advertising information would be sufficient and has revised § 1702.13 accordingly.

One commentor questioned the relevance of requiring marketing history

information at § 1702.14 for all petitions for an exemption.

The Commission believes that marketing history information is important when evaluating exemption requests. This information is important since in establishing the degree of hazard associated with a particular product, it is important to consider the hazard in the context of the overall marketing of the product. The ratio of ingestions to sales may be significant in evaluating the hazard.

(4) *Petitions Requesting an Exemption for a Drug or a New Drug (§ 1702.16)*

Several commentors objected to the provision at § 1702.16(b) that the Commission will deny petitions to exempt new drugs if the FDA has not approved a new drug application. According to one commentor, this provision could lead to delays in making certain new drugs available for use by patients since lead times are necessary for purchasing packaging supplies and materials and for planning and scheduling packaging operations. The commentor suggested that the Commission review petitions and grant a conditional approval pending final approval of the new drug application (NDA). Several commentors stated that since packaging of a new drug is a part of the NDA, and since stability data concerning the packaging must be submitted with the NDA, the Commission should approve a petition conditioned on subsequent approval of the NDA by the FDA.

The Commission has stated in § 1702.8 of the interim rule that human experience data are the primary criteria used by the Commission in evaluating petitions for exemption. Since significant human experience data do not generally exist without an approved NDA, the Commission is unable to consider exemption requests for new drugs without an approved NDA, when an approved NDA is required by FDA. Since manufacturers may submit stability data at both conventional and special packaging at the time they file their NDA with the FDA, the Commission does not believe that § 1702.16(b) would delay the introduction of new drugs. In the event that a manufacturer decides to submit stability data with the NDA on only one type of packaging, the FDA can process supplemental NDA's for other types of packaging within 180 days.

One comment from the Bureau of Veterinary Medicine of the FDA suggested that § 1702.16 be changed to include new animal drugs.

Since veterinary prescription drugs as a class are not currently required to be

in special packaging, the Commission has decided at this time not to amend the exemption procedures to specifically address these drugs. If in the future this class of drugs is required to be in special packaging petitions concerning these drugs must comply with these regulations.

(5) *Additional Comments*

One commentor requested that the term "household substance" at § 1702.1 of the regulations be clarified to indicate whether animal drugs sold for use in commercial feeding operations fall within the meaning of this term. The commentor also requested that § 1702.7 be amended to include, as an additional ground justifying an exemption, the fact that the product is not accessible to young children. The commentor also requested that § 1702.17 be changed to include an additional reason for granting an exemption based on the lack of need for special packaging because of the nature of the product's intended use.

The term "household substance" is defined at section 2(2) of the PPPA (15 U.S.C. 1471) as "any substance which is customarily produced or distributed for sale for consumption or use, or customarily stored, by individuals in or about the household * * *". The Commission believes that animal drugs sold for use in commercial feeding operations that are not accessible to small children do not fall within the meaning of the term "household substance." Since these products and similar products are excluded from coverage by the statutory definition, these products would not be the subject of petitions for exemption under this regulation. As a result, the Commission does not believe that it is necessary to amend the regulation to specifically exclude these products, or to include an additional justification for an exemption based on the fact that a product is not a "household substance."

Several commentors suggested that the regulation specify that information must be included in the petition only where the information is reasonably available to the petitioner.

The purpose of the regulation is to ensure that the Commission obtains sufficient information to evaluate petitions for exemption. The regulation is not intended to overburden petitioners by requiring them to submit information that is unnecessary or not reasonably available. The Commission has changed §§ 1702.3, 1702.5, 1702.8, and 1702.9 to clarify that reasonably available information must be submitted. At § 1702.3(b) the Commission has defined "reasonably available" information as data that is in

the petitioner's possession, data that has previously been generated by the petitioner, and data that is obtainable from such sources as reports from Poison Control Centers, reports of adverse reactions that have been submitted to the petitioner, the medical, pharmacological and toxicological literature, and information required by the FDA for an Investigational Exemption for a New Drug (IND) or a New Drug Application (NDA).

One commentor requested the Commission to clarify whether previously granted PPPA exemptions are affected by the regulation.

The regulation does not affect PPPA exemptions that have been granted.

D. *Effective Date and Withdrawal of Interim Rules*

Petitions for an exemption from special packaging requirements that are received by the Commission after March 31, 1980, must comply with the requirements in this regulation. The Commission will consider petitions received before this date under the present interim regulations for petitions, (42 FR 44802, September 7, 1977). After March 31, 1980, the interim regulations published at 16 CFR Part 1702, (42 FR 44802, September 7, 1977) are no longer in effect as guidelines, and are withdrawn by the Commission.

E. *Conclusion*

Accordingly, under provisions of the Poison Prevention Packaging Act of 1970 (secs. 2(4), 3, 5; Pub. L. 91-601; 84 Stat. 1670-1672; 15 U.S.C. 1471(4), 1472, 1474), the Federal Hazardous Substances Act (sec. 10(a); 74 Stat. 378; 15 U.S.C. 1269(a)), The Federal Food, Drug, and Cosmetic Act (sec. 701(a); 21 U.S.C. 371(a)), and under authority vested in the Commission by the Consumer Product Safety Product Act (Pub. L. 92-573; sec. 30(a); 86 Stat. 1231; 15 U.S.C. 2079(a)), the Commission replaces the existing Part 1702 by adding the following new Part 1702 to Subchapter E. Chapter II:

PART 1702—PETITIONS FOR EXEMPTIONS FROM POISON PREVENTION PACKAGING ACT REQUIREMENTS; PETITION PROCEDURES AND REQUIREMENTS

Sec.	
1702.1	Purpose and policy.
1702.2	Procedural requirements.
1702.3	Substantive requirements.
1702.4	Petitions with insufficient or incomplete information.
1702.5	Failure to supply adverse information.
1702.6	Trade secrets and other confidential information.

Sec.

- 1702.7 Justification for the exemption.
- 1702.8 Human experience data.
- 1702.9 Relevant experimental data.
- 1702.10 Human experimental data involving the testing of human subjects.
- 1702.11 Product specifications.
- 1702.12 Packaging specifications.
- 1702.13 Labeling and Packaging Samples.
- 1702.14 Marketing history.
- 1702.15 Petitions alleging incompatibility of child resistant packaging with the particular substance petitioned for exemption.
- 1702.16 Petitions requesting an exemption for a drug or a new drug.
- 1702.17 Granting petitions.
- 1702.18 Denying petitions.
- 1702.19 Effect of filing petition.

Authority: Secs. 2(4), 3, 5; Pub. L. 91-601; 84 Stat. 1670-72; 15 U.S.C. 1471(4), 1472, 1474; sec. 10(a), 74 Stat. 378; 15 U.S.C. 1269(a); 21 U.S.C. 371(a); sec. 30(a); Pub. L. 92-573, 86 Stat. 1231; 15 U.S.C. 2079(a).

§ 1702.1 Purpose and policy.

(a) Section 1700.14(a) of Part 1700 lists household substances the Consumer Product Safety Commission requires, under section 3(a)(1) of the Poison Prevention Packaging Act of 1970, 15 U.S.C. 1472, to be contained in special packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substances. There may be occasions, however, when the Commission determines that a particular substance should be exempt from special packaging requirements.

(b) The Commission may, either on its own initiative or upon the petition of any interested person, amend the regulation at § 1700.14(a) by exempting a substance or category of substances from special packaging requirements. The purpose of these rules is to provide procedures and requirements for submitting petitions for exemption from special packaging requirements.

§ 1702.2 Procedural requirements and recommendations.

(a) *Requirements.* To be considered a petition for exemption from special packaging requirements under this Part a document filed under this part must:

- (1) Be mailed or delivered to the Office of the Secretary, Consumer Product Safety Commission, 1111 18th Street, NW., Third floor, Washington, D.C. 20207,
- (2) Be written in the English language,
- (3) Contain the name and address of the petitioner,
- (4) Contain an explicit request for exemption from special packaging requirements,
- (5) Identify the category of substances under § 1700.14(a) from which the exemption is sought, and
- (6) Identify the particular substance for which the exemption is sought.

(b) *Failure to meet requirements.*

Where a submission fails to meet all of the requirements of paragraph (a) of this section, the Office of the Secretary shall notify the person submitting it, describe the deficiency, and explain that the petition may be resubmitted when the deficiency is corrected.

(c) *Procedural recommendations.* The following are procedural recommendations to help the Commission in its consideration of petitions. The Commission requests, but does not require, that petitions filed under this part:

- (1) Be typewritten,
- (2) Include the word "petition" in a heading preceding the text,
- (3) Include the telephone number of the petitioner, and
- (4) Be accompanied by at least five (5) copies of the petition.

§ 1702.3 Substantive requirements.

(a) A petition filed under this Part shall include the information required by this part, or a satisfactory explanation for the absence of the information. As provided by § 1702.4, a petition which is not complete may be closed. To be considered complete, a petition shall include the following:

- (1) A statement of the justification for the exemption in accordance with § 1702.7,
- (2) All reasonably available human experience data, reasonably available relevant experimental data (both human and animal), product and packaging specifications, labeling, and marketing history, in accordance with §§ 1702.8 through 1702.14,

(b) As used in this regulation, "reasonably available" information is data in the petitioner's possession; data that has previously been generated by the petitioner, and data that is obtainable from such sources as: Reports from Poison Control Centers; reports of adverse reactions that have been submitted to the petitioner; the medical, pharmacological, and toxicological literature; and information required by the FDA for an Investigational Exemption for a New Drug (IND) or a New Drug Application (NDA).

§ 1702.4 Petitions with insufficient or incomplete information.

If a petition is submitted that is not complete and does not explain the reason for the absence of the information, the Commission shall afford the petitioner a reasonable opportunity to provide additional information. If the required information is not submitted to the Commission, or if the petitioner does not satisfactorily

explain the absence of the information within a reasonable time, the petition shall be closed if insufficient or incomplete information has been submitted to enable the Commission to evaluate the merits of the exemption request.

§ 1702.5 Failure to supply adverse information.

Failure to obtain and provide the Commission with all reasonably available information that the petitioner knows is unfavorable or could reasonably expect to be unfavorable to the petition shall result in the denial of the petition.

§ 1702.6 Trade secrets and other confidential information.

Where a petition contains material that the petitioner believes should be exempt from public disclosure under the Freedom of Information Act, 5 U.S.C. 552, the petitioner shall comply with the requirements of 16 CFR Part 1015, the Commission's regulation under the Freedom of Information Act concerning requests for treatment as exempt material. The Commission shall act upon any request for treatment as exempt material in accordance with the provisions of 16 CFR Part 1015.

§ 1702.7 Justification for the exemption.

The justification for the exemption, required under § 1702.3, shall explain the reason for the exemption based on one or more of the following grounds:

(a) If the justification is based on a lack of need for special packaging to protect young children from serious injury or illness from the substance, the justification shall state how the lack of toxicity and lack of adverse human experience for the substance clearly supports granting the exemption.

(b) If the exemption is requested because special packaging is not technologically feasible, practicable, or appropriate for the substance, the justification shall explain why.

(c) If the exemption is requested because special packaging is incompatible with the particular substance, the justification shall explain why.

§ 1702.8 Human experience data.

Human experience data constitutes the primary criterion used by the Commission in evaluating petitions for exemptions. Petitions shall therefore include a compilation of all reasonably available reports pertaining to human use of the particular substance, including the product brand as well as generic equivalents and involving adverse reports of personal injury, illness, and significant allergenicity.

Such information in children is of particular importance in evaluating exemption requests. However, similar data in adults shall also be submitted if available. Human experience data may be obtained from such sources as:

(a) Reports from Poison Control Centers,

(b) Reports of adverse reactions relative to the product that have been submitted to the company by physicians, hospitals, consumers, and other sources,

(c) Extensive searches of the medical, pharmacological, and toxicological literature, and

(d) For drugs, where the human experience data submitted is based on data required by FDA to be compiled for an Investigational Exemption for a New Drug (IND), 21 CFR Part 312, or a New Drug Application (NDA), 21 CFR Part 314, a summary of the relevant data should be provided. The entire NDA and IND material need not be submitted.

§ 1702.9 Relevant experimental data.

Experimental data are generated in both animals and humans in controlled situations in order to evaluate the biological effects of a substance. Certain toxicological effects cannot generally be evaluated in human beings. This is especially true of those substances which are not normally intended to be used in or on the human body or animal body. Therefore, the Commission considers experimental data obtained in animal studies to be an important supplement to such data as may exist from any experimental studies conducted in humans. The minimum toxicological evaluation necessary for a particular household substance is proportional to the expected exposure of man to that substance. Household substances which are not expected, in normal use, to contact man are subject to less extensive studies than those substances, such as drugs, which are designed to be used in or on man. The Commission has, therefore, separated the requirements of this section into three subsections. Section 1702.9(a) lists minimum acute animal toxicity data which shall be submitted, if reasonably available, for all petitions; § 1702.9(b) lists those additional data which shall be submitted, if reasonably available, for drug products and all other household substances which are normally intended to be used in or on the human body; and § 1702.9(c) lists those additional data which shall be submitted, if reasonably available, by petitioners requesting exemption for substances not intended for use in or on the human or animal body. The Commission emphasizes that, while not

absolutely necessary, the types of data outlined in § 1702.9(c) may greatly expedite the Commission's evaluation of a particular exemption request.

(a) *General criteria applicable to all petitions.* (1) Each petition for an exemption under this Part shall include all reasonably available relevant experimental data relating to the petition regardless of whether such data are unfavorable to the petitioner's request. As used in this part, the term "relevant experimental data" includes, but is not limited to, all data, including animal and human studies revealing the nature and degree of the hazard associated with the particular substance. Generally, the hazard associated with the particular substance involves the risk of injury arising from the acute accidental ingestion of a product. Where a hazard different from the risk of injury arising from accidental ingestion is known to exist (e.g., potential for significant allergenicity, dermal or ophthalmic injury from handling or using the product), the petitioner shall also submit all reasonably available relevant experimental data evaluating the nature and degree of any additional hazard(s).

(2) All animal studies submitted in support of exemption requests should be performed in conformity with good pharmacological and toxicological practice which includes, as a minimum, complete descriptions of protocols used in experimental animal studies, and signed laboratory reports which include the following basic information:

(i) An exact description of materials tested;

(ii) A description of test animals employed in studies, including number, age, weight, sex and nutritional state of animals;

(iii) Dosage level(s) and number of animals tested per dosage level;

(iv) Basis upon which dosage was administered (e.g., as salt or base);

(v) Route of administration and dosage volume; and

(vi) Appendices containing all raw data and any additional data generated subsequent to the completion of the original study (e.g., results of histopathological examinations, if performed).

(3) Each petition shall include all reasonably available reports of Median Lethal Dose (LD50) studies and shall include all raw data obtained in such studies. These studies should normally be conducted in both adult and weanling animals of the same species. The oral route of administration should be followed for studies involving substances subject to regulations promulgated under the Poison

Prevention Packaging Act of 1970. Where a percutaneous toxicity hazard exists, the petition shall include reasonably available studies using the percutaneous route of administration. Sufficient dosage levels as well as adequate numbers of test animals per dosage level should be used to give statistical reliability to determined LD50 values.

(4) In view of the fact that LD50 values in themselves do not necessarily reflect a true estimate of the overall toxic potential of a substance, LD50 determinations should, where an LD50 value may be calculated, include:

(i) The LD50 value with 95 percent confidence limits;

(ii) A slope determination for the dose response curve, including 95 percent confidence limits; and

(iii) A description of the statistical method employed in the analysis of such data (with proper citation) as well as the statistical analysis itself.

(5) The Commission shall disregard any data which do not fulfill the strict requirements of the statistical method used in their analyses. Modifications of accepted statistical methods which have been published in the literature are acceptable to the Commission provided that a copy of the published work is submitted.

(6) Acute toxicity studies submitted with petitions should have at least a seven day observation period of test animals. Good pharmacological practice provides that test animals are observed closely for several hours following test substance administration and less frequently on subsequent test days. Succumbing animals should be necropsied as soon as practicable following death, while surviving animals should be necropsied, and gross pathological alterations noted, at the end of the observation period. Documentation of non-lethal effects occurring during these observation periods should be submitted in conjunction with acute toxicity laboratory reports. Documentation of any lethal effects occurring at high dosage levels, including mode of death (e.g., cardiac arrest/respiratory arrest), and time of death should be submitted in conjunction with acute toxicity laboratory reports. Reports of gross necropsies performed upon surviving animals should be submitted, as well as results of necropsies performed upon animals succumbing to the test substance, provided that such animals are examined prior to the onset of autolysis. Results of microscopic examinations, when indicated by the nature or results of an acute toxicity study, shall also be submitted.

(b) *Additional data criteria for petitions involving substances normally used in or on the human or animal body.*

(1) Petitioners submitting exemption requests for substances normally used on or taken into the human body or animal body shall, in addition to the requirements of paragraph (a) of this section submit the following data, where reasonably available:

(i) Summary laboratory reports of data obtained in subacute and chronic animal studies where the data pertain to the absorption, distribution, metabolism and excretion of substances in question;

(ii) A median lethal dosage (LD50) determination conducted in one additional species. Of the two LD50 determinations required for persons submitting exemption requests under this part, one should be conducted in a nonrodent species;

(iii) Summary reports of data obtained in human studies designed to measure the absorption, distribution, metabolism, and excretion of substances in question; and

(iv) Data indicating, insofar as is known, the mechanism of action of the substance in question and the mechanism by which expected toxicological effects occur. If these mechanisms are unknown, the petition should state this. (2) Petitioners submitting exemption requests for substances normally used on or taken into the human or animal body shall, in addition to the requirements of paragraphs (a) and (b)(1) of this section, submit an evaluation of the pharmacology and toxicology of the substance in question based on reasonably available medical and scientific literature. The evaluation should be a comprehensive one, and should include proper literature citations. To the extent possible, information submitted by the petitioner justifying an exemption based on the medical and scientific literature will be evaluated under the criteria specified in § 1702.9(a) for evaluating experimental data. In certain cases where the experimental data specified by § 1702.9(a) and (b) are unavailable, the medical and scientific literature may justify granting an exemption, particularly where the pharmacology and toxicology of the substance is well documented in the literature.

(c) *Optional data criteria for petitions involving substances not used in or on the human or animal body.* The following types of data, although often not generated for household substances not normally used in or on the human or animal body, may be available to a petitioner and should, where reasonably available, be submitted.

(1) Summary laboratory reports of data obtained in subacute and chronic animal studies where such data pertain to the absorption, distribution, metabolism, and excretion of the substance in question;

(2) Results of median lethal dosage (LD50) studies conducted in additional species of animals; and

(3) Any additional experimental studies relevant to the exemption request which would provide the Commission with additional means of assessing the hazards to children of the product for which exemption is sought.

§ 1702.10 Human experimental data involving the testing of human subjects.

Any human experimental data submitted with a petition requesting an exemption under this part shall include a statement establishing that adequate measures have been taken to ensure against psychological or physical injury to the subject of the human studies. The Commission considers its regulations concerning the protection of human subjects (16 CFR Part 1028) to be an example of measures that are adequate to ensure against psychological or physical injury to human subjects.

§ 1702.11 Product specifications.

Each petition for an exemption shall include:

(a) A complete quantitative formula for the product, including inert ingredients, diluents, and solvents. (Petitioners should refer to § 1702.6 for information regarding trade secrets.)

(b) A listing of all physical forms or dosage forms (whichever is appropriate) in which the product is available.

§ 1702.12 Packaging specifications.

Each petition for an exemption shall include the following information for each form of the product for which an exemption is sought:

(a) A description of the packaging currently in use including the name of the manufacturer of the package and all specifications for the package.

(b) A complete packaging description including any carton or wrapping in which the product is offered to the consumer.

(c) A description of each size in which the product is offered, including physical form, color and flavoring, and

(d) An empty sample of each type and size of package petitioned for exemption and, in the case of drugs, a designation of those packages intended to be used in dispensing the product to the consumer for household use.

§ 1702.13 Labeling and packaging samples.

Each petition for an exemption under this part shall include a sample of the label and complete packaging for each size in which each form of the product for which an exemption is sought is packaged. This shall include the immediate container labeling, any package inserts, and other carton or wrapping labeling in which the product is offered to the consumer. In the case of drugs, each petition shall be accompanied by labeling on the outer carton or wrapping in which the product is offered to the retailer, as well as samples of the promotional and advertising information for the product.

§ 1702.14 Marketing history.

Each petition for an exemption under this Part shall include a statement of the marketing history of the substance for which an exemption is requested. The marketing history dates from the year in which each form of the product was introduced onto the market. The marketing history shall include the total number of units of each form or strength and package size of the product distributed since the product was introduced onto the market. In the case of prescription drugs, the average prescription size for the product should also be indicated, if known.

§ 1702.15 Petitions alleging the incompatibility of child resistant packaging with the particular substance petitioned for exemption.

(a) Where the petition for an exemption is based upon an allegation that the applicable special packaging standard is incompatible with the particular substance or would seriously and adversely compromise the utility or stability of a substance, the petitioner shall submit adequate evidence to support the allegation.

(b) If the allegation of incompatibility is based upon the fact that package choice is limited by a new drug application filed with the FDA, the petition shall state the limitation of package choice and a description of a time schedule to revise the NDA in order to allow additional package choice.

(c) If the allegation of incompatibility is based upon the fact that the shelf life of the product limits package choice, the petition shall outline the particular limitation and shall include a description of a time schedule to re-establish shelf-life data.

§ 1702.16 Petitions requesting an exemption for a drug or a new drug.

(a) Where the petition requests an exemption for a drug, as defined in

section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), the petitioner shall include those reports required to be filed under the Food and Drug Administration's Adverse Reaction Reporting Program.

(b) Where the petition requests an exemption for a new drug, as defined in section 201(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(p)) the Commission shall deny the petition if the Food and Drug Administration has not, where required by FDA, approved a new drug application.

§ 1702.17 Granting petitions.

Where the Commission determines that reasonable grounds for an exemption are presented by the petition, the Commission shall publish, in the *Federal Register*, a proposed amendment to the listing of substances requiring special packaging under § 1700.14(a). "Reasonable grounds" for publishing a proposed exemption are information and data sufficient to support the conclusion that:

(a) The degree or nature of the hazard to children in the availability of the substance, by reason of its packaging, is such that special packaging is not required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting the substance, or

(b) Special packaging is not technically feasible, practicable, or appropriate for the subject substance, or

(c) Special packaging is incompatible with the particular substance.

§ 1702.18 Denying petitions.

Where the Commission determines that reasonable grounds for an exemption are not presented by the petition, the petition shall be denied, and the petitioner notified in writing of the denial, including a brief statement of the reasons therefor.

§ 1702.19 Effect of filing petition.

The filing of a petition for exemption under this Part 1702 shall not have the effect of staying the regulation from which the exemption is sought. Therefore, substances subject to special packaging standards shall be considered in violation of the law unless packaged in special packaging during the Commission's consideration of a petition.

Dated: February 20, 1980.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 80-6156 Filed 2-27-80; 8:45 am]

BILLING CODE 6355-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 282

[Docket No. RM79-14]

Regulations Implementing the Incremental Pricing Provisions of the Natural Gas Policy Act of 1978; Order Denying Hearing

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Order Denying Rehearing.

SUMMARY: The Federal Energy Regulatory Commission hereby issues an order in response to petitions which were filed requesting rehearing or clarification of Order No. 49-A, a rehearing order on the final regulations implementing the incremental pricing program mandated by the Natural Gas Policy Act of 1978. This order denies rehearing of Order No. 49-A.

EFFECTIVE DATE: February 21, 1980.

FOR FURTHER INFORMATION CONTACT: Barbara K. Christin, Federal Energy Regulatory Commission, 825 North Capitol Street N.E., Washington, D.C. 20426, (202) 357-8079.

February 21, 1980.

I. Filed Petitions

On September 28, 1979 (44 FR 57725, October 5, 1979), the Federal Energy Regulatory Commission (Commission) issued in Order No. 49 final regulations which implement portions of the first phase of the incremental pricing program. Subsequently, sixteen petitions for rehearing, reconsideration, modification, or clarification of Order No. 49 were filed with the Commission. On December 27, 1979 (45 FR 767, January 3, 1980), an order on rehearing, Order No. 49-A, was issued in response to these petitions.¹

Timely petitions for rehearing of Order No. 49-A were filed by Man-Made Fiber Producers Association, American Hardboard Association, Process Gas Consumers Group, *et al.*,²

¹ Order Granting in Part and Denying in Part Petitions for Rehearing, Reconsideration, Modification, or Clarification; Amending Regulations, and Denying Motions to Waive Regulations and Accept Late-Filed Petitions.

² The joint petition filed by Process Gas Consumers Group, American Iron and Steel Institute, and the Georgia Industrial Gas Group included an alternative request for reconsideration.

Allied Chemical Corporation,³ and The Fertilizer Institute.⁴

The Commission has considered the arguments raised in these filings. Based on this analysis, the Commission has determined to deny rehearing of Order No. 49-A.

II. Issues Raised in Petitions

A. Definition of Agricultural Use

Man-Made Fiber Producers Association and American Hardboard Association requested that the definition of agricultural use set forth in § 282.202(a) of the regulations be amended by the addition of certain Standard Industrial Classification (SIC) Codes. In addition, Man-Made Fibers requested that the Commission determine the processing of cellulosic man-made fibers to be "natural fiber processing."

As a result of these filings, and several submissions which have been made to the Commission under § 1.41 of its regulations with regard to the definition of "agricultural use," the Commission believes it would be appropriate to give full consideration to the question of what SIC Codes, if any, should be added to the agricultural use list in § 282.202(a) of the Commission's regulations. For this reason, a new docket, Docket No. RM80- will be opened to receive comments on the possible expansion of the list of SIC Codes considered to be agricultural uses for purposes of incremental pricing. In this way, all possible requests for inclusion in the list of agricultural uses will be consolidated in a single docket, which will enable the Commission to dispose of them in a consistent manner.

The Commission therefore denies the petitions for rehearing on this matter. The information contained in the requests for rehearing, however, will be made part of the record in Docket No. RM80-. A separate notice announcing the opening of this docket and setting a deadline for the submission of comments will be issued in the near future.

B. Natural Gas Used as Boiler Fuel in the Production of Fertilizer

In Order No. 49-A the Commission announced the opening of Docket No. RM80-18 to receive comments on whether a rulemaking proceeding should be instituted by the Commission to define certain boiler uses of natural gas

³ The petition of Allied Chemical was styled as a Motion for Clarification or Application for Rehearing.

⁴ The petition of The Fertilizer Institute was styled as a Request for Clarification or Application for Rehearing.