Implementation Of The Poison Prevention Packaging Act Of 1970

B-164031(2)

Food and Drug Administration
Department of Health, Education,
and Welfare

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

MAY 15, 1973

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-164031(2)

The Honorable Joseph M. Montoya
United States Senate

Dear Senator Montoya:

This is our report on the implementation of the Poison Prevention Packaging Act of 1970 by the Food and Drug Administration, Department of Health, Education, and Welfare.

Public Law 92-573 (86 Stat. 1207), dated October 27, 1972, establishes the Consumer Product Safety Commission and transfers the responsibility for implementation of the Poison Prevention Packaging Act to the Commission. As of April 30, 1973, the transfer had not been effected.

We made our review pursuant to your request of January 5, 1972, and subsequent discussions with your office. As agreed upon with your office, we obtained formal written comments from the Department on the report.

We plan no further distribution of this report unless you agree or publicly announce its contents.

Sincerely yours,

Elmer B. Staats

Comptroller General
of the United States

Contents

ABBREVIATIONS

BPS	Bureau of Product Safety
FDA	Food and Drug Administration
GAO	General Accounting Office
HEW	Department of Health, Education, and Welfare
NEISS	National Electronic Injury Surveillance System
PPPA	Poison Prevention Packaging Act of 1970

COMPTROLLER GENERAL'S REPORT TO THE HONORABLE JOSEPH M. MONTOYA UNITED STATES SENATE

IMPLEMENTATION OF THE POISON PREVENTION PACKAGING ACT OF 1970

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D I G E S T

WHY THE REVIEW WAS MADE

Senator Joseph M. Montoya asked GAO to review the implementation of the Poison Prevention Packaging Act of 1970 (PPPA).

Background

The Food and Drug Administration (FDA), Department of Health, Education, and Welfare (HEW), is responsible for carrying out PPPA. It requires safety closures and other safety packaging to protect young children from accidently swallowing toxic or harmful household substances.

PPPA authorized the Secretary, HEW, to establish standards requiring special packaging of foods, drugs, cosmetics, pesticides, fuels, and other certain household products which are poisonous or harmful if swallowed. Special packages must resist opening by children under 5 years but open easily for adults. (See p. 5.)

PPPA provided that the Secretary consult a technical advisory committee--scientists, doctors, consumers, and representatives from Government and industry--before establishing standards for such packaging. (See p. 6.)

FDA expended about 4.3 man-years on PPPA activities in fiscal year 1972 and estimated that it would expend about 12 man-years in fiscal year 1973. FDA budgeted about $700,000 and $800,000 in fiscal years 1972 and 1973, respectively, for PPPA salaries, contracts, and administrative and operating expenses. (See p. 7.)

About 136,000 ingestions of harmful products commonly found in and around the household were reported to FDA in calendar year 1971. About 62 percent (84,000) involved children under 5 years, including some 4,900 cases in which the children were hospitalized for treatment. About 4,000 of the 84,000 cases and 100 of the 4,900 hospitalizations were ingestions of items not susceptible to packaging, such as plants and toadstools. (See p. 5.)

FINDINGS AND CONCLUSIONS

As of December 1, 1972, FDA had issued seven packaging standards--three not to become effective until April 11, 1973--and had proposed four others. (See p. 12.)

These standards cover products involved in 52 percent of the 80,000 ingestions by children under 5 years of age of products susceptible to packaging reported to FDA in calendar year 1971. These standards also

cover products involved in 73 percent of the reported 4,800 ingestions of products susceptible to packaging which resulted in children's being hospitalized. (See pp. 14 and 15.)

FDA extended to January 22, 1973, the effective date of the standards requiring retail pharmacists to dispense prescription drugs that contain aspirin, methyl salicylate, or controlled drugs in special packing. This extension was granted because manufacturers were unable to supply enough special packages to retail pharmacists. It applied only to retail pharmacists who ordered special packaging well in advance of the effective dates. Special packages must be used as soon as they become available. (See p. 12.)

Establishing special packaging standards

To meet PPPA requirements FDA established a procedure for testing the packages. This defines the method to be followed by package manufacturers in testing packages, as well as the procedure to be used by FDA in determining the adequacy of packages.

The testing procedure requires that 200 children, ages 42 to 51 months, evenly selected as to age and sex, be given time to gain access to the contents of the special package. The package also must be tested on 100 adults, age 18 to 45 years, of whom 70 percent are female. The adults are given 5 minutes to open and close a package properly. (See p. 8.)

The four standards in effect as of December 1, 1972, required an average of about 15 months (including 8 months of mandatory waiting periods) for FDA to process.

FDA uses a procedure authorized by PPPA to establish standards for special packaging. This procedure requires that FDA obtain information on the need for a standard, draft the proposed standard, review it for legal and policy considerations, consider comments from interested persons, and make any necessary revisions. These steps took an average of about 7 months for the four standards.

The procedure also requires publishing the proposed standard in the Federal Register and allowing 60 days for interested persons to comment. After FDA considers the comments, the standard is finalized and again published in the Federal Register and goes into effect 180 days after publication unless the Secretary, HEW, determines an earlier effective date is in the public interest. These requirements account for the remaining 8 months it took to finalize the four standards. (See p. 10.)

Technical advisory committee

On April 29, 1971, HEW established the technical advisory committee for poison prevention packaging, which the Secretary, HEW, must consult before establishing any standards for special packaging. PPPA does not authorize the committee to approve or veto the standards.

The committee consists of up to 18 members representing

--HEW,

--the Department of Commerce,

--manufacturers of household

substances subject to PPPA,

--scientists with expertise related to PPPA and licensed practitioners in the medical field,

--consumers, and,

--packaging and closure manufacturers. (See p. 16.)

As of January 1973, the committee had held seven meetings to discuss the status of the standards and plans and problems associated with special packaging of other household products, as well as other substantive and procedural matters. (See pp. 18 and 19.)

In addition, FDA consults extensively with the committee through correspondence. Members are each provided information by FDA on the hazards of each product being considered for special packaging.

Committee members are requested to provide to FDA, within 3 weeks, advice or information concerning the (1) reasonableness of proposing a standard, (2) scientific, medical, and engineering data pertaining to the product, (3) manufacturing practices of affected industries, and (4) nature and use of the product in the household. (See p. 17.)

Development of special packages

According to FDA, developing a special package involves three stages--design and feasibility, test and evaluation, and production and distribution. FDA said it is a costly process and different-sized packages, as well as changes in package materials or design, could affect production and it may have to be repeated. (See p. 20.)

Product manufacturers questioned the ability of packaging manufacturers to supply enough special packages within a reasonable period and at a reasonable cost. As a result, FDA conducted a 20-firm survey, completed in January 1972.

FDA concluded that enough special packaging would be available for most products by the effective date of the applicable standards. As previously noted, however, problems were encountered and FDA extended the effective date for certain products because of an inadequate supply of packages. (See p. 21.)

Poison control centers and National Electronic Injury Surveillance System

Poison control centers provide information to physicians, hospitals, and the public about treating and preventing poisonings. Generally the centers are located in, and funded by, hospitals.

About 500 of the 580 centers voluntarily submit reports to FDA on poisonings. FDA uses these reports to determine those products which should be special packaged and to set priorities for establishing standards. (See pp. 21 and 22.)

FDA considers the centers better sources of information on poisonings than its National Electronic Injury Surveillance System (NEISS). This is a system of 119 statistically selected hospital emergency rooms that submit daily reports, which supplement the centers' reports, of product injuries to help develop statistically valid injury data.

According to FDA, NEISS reports do not provide sufficiently detailed information on the products ingested

and circumstances surrounding the poisonings to be relied on exclusively. (See p. 23.)

AGENCY ACTIONS

According to HEW, GAO's report fairly presents FDA efforts to implement PPPA. (See p. 27.)

CHAPTER 1

INTRODUCTION

The Poison Prevention Packaging Act of 1970 (PPPA) (15 U.S.C. 1471) was enacted December 30, 1970, to protect young children from accidentally ingesting toxic household substances by requiring safety closures and other safety packaging for such substances. PPPA applies to all products customarily stored in and around the household and includes foods, drugs, cosmetics, pesticides, fuels in portable containers, and cleaning products. The Food and Drug Administration (FDA), Department of Health, Education, and Welfare (HEW), administers PPPA.

In calendar year 1971 about 136,000 ingestions of products commonly found in and around the household were reported to FDA. Of these, about 84,000, or about 62 percent, involved children under 5 years of age, including about 4,900 cases in which children were hospitalized for treatment. Many cases treated by parents, private physicians, or hospitals were not reported. About 4,000 of the 84,000 ingestions and 100 of the 4,900 hospitalizations were ingestions of items not susceptible to packaging, such as plants and toadstools.

PPPA authorizes the Secretary, HEW, to establish standards requiring special packaging for any household substance containing a toxic or harmful substance that could cause serious personal injury or illness to children if, because of its packaging, that substance is accessible to children. Standards must be feasible as to packaging technology, adaptable to mass-production, and appropriate to maintain the integrity of the packaged material.

Special packaging standards are intended to be performance, not design, standards. The design of special packaging is left to manufacturers or packagers, but the packaging must make it significantly difficult for children under 5 years of age to open or to obtain a toxic or harmful amount of the substance. However, special packaging does not mean packaging which all such children will be unable to open or to obtain a toxic or harmful amount within a reasonable time. Also, special packaging must not be too difficult for normal adults to use properly.

PPPA makes one exception to the special packaging requirements for the benefit of the elderly and the handicapped. One package size of each brand of a product may be marketed in a noncomplying package if the product is also marketed in a special package. The noncomplying package must be conspicuously labeled as intended for households without young children.

PPPA provides that inventories of products packaged before the effective date of the standard may be marketed. Standards will not be effective sooner than 180 days or later than 1 year after being made final unless the Secretary, HEW, determines an earlier effective date is in the public interest.

Household substances not packaged or labeled in accordance with standards established under PPPA are considered misbranded and subject to the misbranding provisions of either the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301); the Federal Hazardous Substances Act (15 U.S.C. 1261); or the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 135). FDA administers the first two acts and the Environmental Protection Agency administers the third.

When misbranded products are found, FDA or the Environmental Protection Agency can initiate one or more of the following legal actions through the Department of Justice.

--Prosecute an individual who violates the acts.

--Enjoin a plant or individual to perform or not perform some act.

--Seize any misbranded product when introduced into or while in interstate commerce.

PPPA also requires the Secretary, HEW, to appoint a technical advisory committee, which he must consult before establishing special packaging standards.

Policies and procedures for PPPA activities are established at FDA headquarters in Rockville, Maryland, and the day-to-day operations are carried out by 10 regional offices and 19 district offices throughout the United States

and Puerto Rico. FDA's Bureau of Product Safety (BPS) implements PPPA and promulgates the required standards.

As of June 30, 1972, BPS had three headquarters employees assigned full time to PPPA activities, and an additional employee was to be assigned in fiscal year 1973. In fiscal year 1972 FDA's field offices expended 1.3 man-years on PPPA activities, and FDA has estimated that in fiscal year 1973 the field offices will expend 8.3 man-years.

The fiscal year 1972 FDA budget was in final preparation when PPPA was passed in December 1970 and did not include funds to implement the act. To implement PPPA in fiscal year 1972, FDA obtained congressional approval to use $700,000 which had been budgeted for other FDA activities. FDA's budget for fiscal year 1973 includes $800,000 for PPPA activities. These funds are primarily for salaries, contracts, and administrative and operating expenses.

We reviewed legislation, regulations, policies, procedures, and practices relating to FDA's poison prevention packaging activities. We also examined records and interviewed agency officials who administer the poison prevention packaging program. Our review was made at the FDA headquarters in Rockville and at BPS in Bethesda, Maryland.

CHAPTER 2

ESTABLISHMENT OF SPECIAL PACKAGING STANDARDS

As of December 1, 1972, FDA had issued seven standards--three of which will not become effective until April 11, 1973--and had proposed four others.[1] These 11 standards cover products that were involved in 52 percent of the 80,000 ingestions by children under 5 years of age of products susceptible to packaging reported to FDA in calendar year 1971. These standards also cover products involved in 73 percent of the reported 4,800 ingestions of products susceptible to packaging which resulted in children's being hospitalized.

TESTING PROCEDURE FOR SPECIAL PACKAGING

To implement PPPA, FDA established a procedure for testing special packages. It sets forth the method to be followed by package manufacturers in testing their packages, as well as the procedure to be used by FDA in evaluating the adequacy of packages.

The testing procedure was based on a protocol developed by an FDA-industry committee established to review safety packaging. The committee's report, submitted to the Commissioner, FDA, on December 7, 1970, concluded that a testing procedure would provide the most effective approach toward evaluating safety closures.

In May 1971 the proposed procedure was submitted to the technical advisory committee for review and comment. After obtaining the committee's general concurrence, the proposed procedure was published in the Federal Register on July 20, 1971, to obtain comments of interested persons.

In August 1971 FDA received comments from 14 individuals or firms. In three cases the comments suggested that the proposed procedure also provide for testing unit packaging. Unit packages are special packages which generally contain a single unit or dose of a product. FDA revised the

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[1] As of February 28, 1973, FDA had issued nine standards and had proposed five others.

procedure to provide for unit packaging and published it in the Federal Register November 20, 1971. The procedure became effective on January 19, 1972.

The testing procedure (21 CFR 295) requires that, for packaging other than unit packaging, 200 children aged 42 to 51 months inclusive, evenly distributed by age and sex, be given 5 minutes each to open the package without any instructions. The procedure also provides that, for testing unit packaging, the 200 children be allowed 10 minutes to open more than five individual units or to obtain access to the number of units which constitutes a toxic amount, whichever is less. Those children who have not opened a package during the first 5 minutes are given a single visual demonstration on how to open the package and are instructed that they may use their teeth. They are then allowed an additional 5 minutes to open the package.

The package must also be tested on 100 adults, age 18 to 45 years inclusive, of whom 70 percent are female. The adults are given only the printed instructions on the package label and are allowed 5 minutes to open and properly close the package.

The procedure requires that package manufacturers maintain records of test results and recommends that they submit the results to FDA. According to an FDA official, PPPA does not authorize FDA to require manufacturers to submit results to FDA. However, as of December 1972, FDA had, except in one instance, received results for all packages required to be submitted to FDA as samples of special packages which are to be marketed. FDA informed us that, for the one instance where FDA did not receive the results, it would contact the manufacturer to request that they be submitted.

ADULT-USE AND CHILD-RESISTANT EFFECTIVENESS

Each of the special packaging standards stipulates the percent of adult-use effectiveness and child-resistant effectiveness required and, where appropriate, other conditions deemed necessary.

FDA established that at least 90 percent of the 100 adults tested must, without a demonstration, be able to open

the special packaging, including unit packaging, and, if appropriate, resecure it.

The child-resistant-effectiveness standards require that (1) at least 85 percent of the children tested be unable to open or gain access to the product before a demonstration on how to open the special package, and (2) at least 80 percent of the children be unable to open or gain access to the package after the demonstration. In the case of unit packaging, at least 80 percent of the children must be unable to open or gain access to more than five individual units or the number of units that constitutes a toxic amount, whichever is less.

In addition, the standard for certain liquid furniture polishes containing petroleum distillates requires that the package restrict the flow of liquid so that not more than 2 milliliters of the contents--less than one-tenth of an ounce--can be obtained when an inverted opened container is shaken or squeezed once or when the container is otherwise activated once.

PROCEDURE FOR ESTABLISHING STANDARDS

FDA used the procedure authorized by PPPA to establish standards for special packaging. The following outline explains the general steps followed by FDA to develop, publish, and finalize a standard.

--BPS collects data on products being considered for standards. It (1) considers data from poison control centers, (2) considers the product and its packaging, (3) considers all pertinent material in the medical literature, (4) consults with experts on such products, (5) consults with the staffs of other bureaus and Federal agencies that are interested in these products, and (6) compiles the data which will support the need for special packaging. The data is sent to the technical advisory committee members for their consideration and comments on the reasonableness of establishing a standard. BPS evaluates the committee's comments and sends each member a summary of them.

--BPS then prepares a proposed standard that includes a preamble announcing the proposed action, the legislative authority for the proposed standard, and the reasons for such action. The proposed standard is forwarded to the Office of the Commissioner, FDA, to be reviewed for policy and legal considerations.

--After being approved for policy and legal considerations, the proposed standard is signed by the Commissioner, FDA, and published in the Federal Register. Interested persons have 60 days from the date of publication to comment. (Before January 4, 1972, only 30 days were provided.) Comments received after 60 days are considered, provided that at the time of receipt the proposed standard has not been finalized.

--Comments are received by the FDA Hearing Clerk and forwarded to BPS for evaluation. If major revisions based on the comments are necessary, BPS prepares a new proposal and publishes it in the Federal Register, allowing an additional 60 days for comment. Otherwise a draft of the proposed standard is finalized.

--The final draft is forwarded to the Commissioner for review and approval.

--The approved standard is published in the Federal Register. Those adversely affected by the standard may, within 60 days after publication, file with the appropriate court of appeals a request for a review of the standard. The effective date is specified in the standard and is not less than 180 days or more than 1 year after publication, unless the Secretary, HEW, determines an earlier date is in the public interest.

The first four standards processed by FDA under this procedure required an average of about 15 months from the time the standard was sent to the technical advisory committee to the effective date. About 7 months were required for FDA to develop, draft, review, and revise the standard. The 60 days allowed for comments and 180 days required before the standard may become effective account for the remaining 8 months.

STATUS OF STANDARDS

As of December 1, 1972, four standards had become effective. The standards cover:

--Preparations containing aspirin (37 F.R. 3427, February 16, 1972; effective August 14, 1972).

--Certain liquid furniture polishes containing petroleum distillates (37 F.R. 5613, March 17, 1972; effective September 13, 1972).

--Certain liquid preparations containing more than 5 percent methyl salicylate (37 F.R. 6184, March 25, 1972; effective September 21, 1972).

--Preparations subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801) (37 F.R. 8433, April 27, 1972; effective October 24, 1972).

Because packaging manufacturers were unable to supply enough special packages to retail pharmacists, FDA extended to January 22, 1973, the effective date for prescription drugs containing aspirin, methyl salicylate, or controlled drugs. This extension applied only to retail pharmacists who ordered special packages well in advance of the effective dates. Special packages must be used as soon as they become available.

As of December 1, 1972, FDA was considering extending the effective date to February 16, 1973, for these products to all persons provided that (1) documentation showed packaging had been ordered before the effective date but had not been received, (2) packaging used is labeled as not being child-resistant packaging, and (3) special packaging is used upon delivery. Because PPPA requires that standards be effective not later than a year from the date the final order is issued, the aspirin standard issued on February 16, 1972, must be implemented not later than February 16, 1973. The extension for prescription drugs containing methyl salicylate and controlled drugs may be further extended to March 25, 1973, and April 27, 1973, respectively.

In addition, FDA has published proposals to exempt certain aspirin products and certain controlled drugs from compliance with the applicable packaging standard because evidence has shown that these products have not presented hazards to children.

On October 13, 1972, FDA issued as a final order three standards which will be effective April 11, 1973. They concern:

--Household substances containing sodium and/or potassium hydroxide (37 F.R. 21633, October 13, 1972).

--Liquid household substances containing 10 percent or more of turpentine (37 F.R. 21635, October 13, 1972).

--Liquid household substances containing 4 percent or more of methyl alcohol (37 F.R. 21632, October 13, 1972).

In addition, FDA published for comment four proposed standards, which cover:

--Liquid kindling and/or illuminating preparations containing 10 percent or more of petroleum distillates (37 F.R. 7408, April 14, 1972).

--Household substances containing 10 percent or more of sulfuric acid (37 F.R. 7809, April 20, 1972).

--Human oral prescription drugs (37 F.R. 8461, April 27, 1972).

--Economic poisons under the Federal Insecticide, Fungicide, and Rodenticide Act (37 F.R. 18629, September 14, 1972).

Comments on the proposed standard for economic poisons were received from September through November 1972. As of January 1, 1973, BPS was revising this proposed standard on the basis of the comments.

Comments on the other three proposed standards were received from April through July 1972. The one for liquid kindling and/or illuminating preparations was revised on the

basis of the comments and was forwarded to the Commissioner on December 19, 1972, for review and approval. Those for sulfuric acid and human oral prescription drugs were being reevaluated as of January 1, 1973, on the basis of comments.

A BPS official told us that the approximately 6-month delay in finalizing the three proposed standards was due to the higher priority given to revising existing regulations rather than to finalizing proposed standards. He stated that the revisions include extensions of the effective dates, exemptions of certain products from the standards, and changes to the testing procedure.

BPS had initially considered packaging standards for individual drug products and had begun developing standards for four of them. Subsequently, however, the technical advisory committee in September 1971 recommended that a single comprehensive standard be established for all human oral prescription drugs that exceed a certain toxicity level. FDA's Bureau of Drugs recommended in December 1971 that all oral prescription drugs, without regard to toxicity, and most nonprescription drugs be covered by one standard.

On March 28, 1972, the Bureau of Drugs' recommendation for a comprehensive standard for all oral prescription drugs was accepted.

On June 20, 1972, FDA published in the Federal Register a request for comments on establishing standards for the special packaging of all nonprescription drugs.

FDA officials advised us that FDA has proposed standards for iron salts, paint solvents, antifreeze, and pine oil and is considering the need for standards for promotionally distributed or mailed samples of household substances.

COVERAGE OF PRODUCTS INGESTED

According to FDA, products involved in about 80,000 of the 84,000 accidental ingestions by young children in calendar year 1971 are susceptible to packaging. Items ingested by children but not susceptible to packaging included plants, carbon monoxide and other vapors, mushrooms, and toadstools. Ingestions of these items, found in and around the household, cannot be controlled under PPPA. BPS

categorized the products susceptible to packaging into 78 groups, such as antihistamines and cold preparations, baby aspirins, vitamins and minerals, and pesticides.

Our analysis showed that the 11 final or proposed standards cover products involved in about 41,200 ingestions, about 52 percent of the 80,000 accidental ingestions. In addition, of the 4,800 cases of hospitalizations resulting from ingestions of products susceptible to packaging, about 3,500, or 73 percent, involved products which would be or are covered by the 11 standards.

CHAPTER 3

TECHNICAL ADVISORY COMMITTEE

ON POISON PREVENTION PACKAGING

PPPA requires the Secretary, HEW, to establish a technical advisory committee, which he must consult before establishing any standards for special packaging. It may have up to 18 members representing (1) HEW, (2) the Department of Commerce, (3) manufacturers of household substances subject to PPPA, (4) scientists with expertise related to PPPA and licensed practitioners in the medical field, (5) consumers, and (6) manufacturers of packages and closures for household substances.

The Senate Committee on Commerce, in its report on the Poison Prevention Packaging Act (S. Rept. 91-845, 91st Cong., 2d sess.), stated that it intended that Department of Commerce representatives be from the National Bureau of Standards and that the chairman of the technical advisory committee be one of the nonindustry members.

ESTABLISHMENT OF COMMITTEE

On April 29, 1971, about 4 months after enactment of PPPA, HEW established the committee.

On February 18, 1971, BPS prepared and submitted to the Commissioner the initial list of nominees and alternates, compiled from recommendations of industry groups, professional societies, the Consumer Advisory Council, and interested individuals. The list was returned to BPS with a request that it be revised to provide more representation for consumers, scientists, and medical groups. A revised list was submitted on March 9, 1971.

On April 5, 1971, after considering the revised list, FDA submitted its nominations to HEW, along with the biographical information required by HEW for individuals serving as members of advisory committees. Subsequently, at the suggestion of HEW that the nominees represent a broader geographical area, FDA added two more names to the list.

Fourteen of the 18 members appointed were nominated or listed as alternate choices by FDA. HEW appointed the other members. Initially, the committee was composed of one representative from HEW, two representatives from Commerce, three manufacturers of household substances, five scientists and licensed medical practitioners, four consumers, and three packaging manufacturers.

On July 1, 1972, HEW revised the committee membership to provide more representation for consumers. Appendix I lists all members that have served on the committee, their terms of appointment and affiliations, and the number of meetings they attended.

PROCEDURES FOR OBTAINING COMMITTEE VIEWS

Generally, the committee's participation in implementing PPPA has involved commenting on data provided by BPS on the hazards of each product being considered for special packaging. Members are requested to provide, within 3 weeks, information or advice concerning the (1) reasonableness of proposing a standard, (2) scientific, medical, and engineering data pertaining to the product, (3) manufacturing practices of affected industries, and (4) nature and use of the product in the household. Members mail their comments to FDA, which evaluates them and sends a summary of them to all members. PPPA does not authorize the committee to approve proposed standards or veto the actions of the Secretary.

BPS officials concluded that the quickest way to implement PPPA was to request individual written responses from members so that their comments could be incorporated, to the appropriate extent, in a proposed standard. These officials stated that it was unreasonable to have members make frequent trips to Washington, D.C., for meetings to review each proposed standard because the members have other responsibilities and some serve without pay.[1]

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[1]PPPA authorizes a $100 a day honorarium and reimbursement of travel expenses for members, except for industry representatives and full-time employees of the United States appointed to the committee, who receive reimbursement for only travel expenses.

COMMITTEE MEETINGS

The committee meets when necessary to discuss the status of standards and plans and problems associated with special packaging, as well as other substantive and procedural matters. Although meetings are not required to satisfy the requirement that the Secretary, HEW, consult the committee, FDA and the committee consider the meetings an essential part of the members' participation in implementing PPPA. As of January 1973, the committee had met seven times.

Executive Order No. 11671, dated June 5, 1972 (37 F.R. 11307), requires all meetings of advisory committees to be open to the public. An exception may be made subject to a written determination by the department or agency head that members will be discussing trade secrets or privileged or confidential matters. Records of all advisory committee meetings are also required.

The meetings held in July and October 1972, after the effective date of Order 11671, were open to the public. Detailed minutes of the meetings were made available for purchase by the public.

Five earlier meetings between May 1971 and April 1972 were not open to the public; however, the public was invited to attend question and answer sessions during four of these meetings. According to BPS officials, these were closed to the public to (1) permit discussion of matters considered confidential, (2) insure candid discussion by members, and (3) minimize interruptions.

Detailed minutes were prepared for only the first two of the five meetings and then the practice was discontinued because, according to BPS officials, it was too costly and the minutes were not considered particularly useful. However, a summary of each meeting was sent to members and is available to the public upon request.

Highlights of meetings

In the first meeting, on May 13 and 14, 1971, FDA officials presented a legislative history of PPPA and defined the committee's role in implementing it. Committee members

and FDA officials discussed methods of testing special packages and the committee recommended adopting a test procedure.

On September 16 and 17, 1971, a status report on substances recommended for special packaging was presented to the members, who discussed some special problems that could be associated with implementating PPPA.

The members also discussed, in this meeting and in the third meeting, on December 9, 1971, developing alternative testing methods, such as mechanical testing, child-resistant-effectiveness standards, and special packaging for oral prescriptions.

In the fourth meeting, on February 17 and 18, 1972, members discussed other FDA poison prevention activities and the role of FDA's Bureau of Drugs in implementing PPPA. BPS officials stated that manufacturers would be responsible for insuring that their packages meet PPPA requirements; however, FDA would monitor the packages through field investigations and reports from poison control centers.

Members and BPS officials discussed during the fifth meeting, on April 27 and 28, 1972, past actions and accomplishments and future plans. Also a study designed to test the manual and oral strengths of children 3 to 6 years of age was discussed. The conclusion was that children are extremely strong and, therefore, strength of the closure alone cannot be considered the basic factor in closure design.

During the sixth meeting, on July 13 and 14, 1972, the Committee recommended that FDA allow the use of an alternative test procedure that would reduce the number of adults and children required to test the special package and revise the age distribution of the children.

At the seventh meeting, on October 5 and 6, 1972, the committee discussed the possibility of proposing standards for additional products and suggested that the effective dates for requiring pharmacists to dispense prescription drugs containing aspirin, methyl salicylate, or controlled drugs in special packages be extended because of problems of retail pharmacists in obtaining enough packages.

CHAPTER 4

OTHER MATTERS PERTAINING TO THE POISON PREVENTION PACKAGING PROGRAM

This chapter presents information concerning the development of child-resistant packages, poison control centers, the National Electronic Injury Surveillance System (NEISS), and instructions provided to FDA field inspectors to implement and enforce the PPPA.

DEVELOPMENT OF SPECIAL PACKAGES

BPS officials categorized development of a special package into three stages--design and feasibility, test and evaluation, and production and distribution.

They informed us that in the first stage the design is conceived; architectural and engineering drawings are made; and models of the package are prepared, evaluated, and revised.

In the second stage a contract is generally awarded to produce a sample mold to make a limited number of packages. According to a BPS official, a package manufacturer usually has these packages tested using a small number of children to evaluate the package design and its ability to resist opening by children. He stated that, once a manufacturer is reasonably certain that a package will meet the requirements of the testing procedure, the manufacturer expands the test to the required 200 children and 100 adults.

A BPS official told us that the expanded test may be made on packages produced from the sample mold or from a production mold. Test results are evaluated and, where necessary, modifications are made to the mold to correct deficiencies.

Also during the second stage, arrangements must be finalized for distributing the package to the purchaser in time to meet production requirements of the product requiring the package. A BPS official stated that, because of the high costs, most packaging manufacturers would not normally undertake development or production of a new package design without some financial guaranty or purchase agreement from the user.

The third stage involves constructing a production mold which would incorporate modifications based on test results. An operating production line must be installed or an existing production line modified and test runs must be made to insure that the line is operational and the product is of acceptable quality.

According to a BPS official, designing and producing a new package is costly. He stated that different-sized packages, as well as changes in package materials or design, could affect production and it may have to be repeated.

Product manufacturers told FDA that not enough special packages would be available in time to meet anticipated effective dates of standards. Consequently, FDA surveyed 20 firms--18 package manufacturers and 2 research firms--on November 9, 1971, to determine what type of safety closures were available and the number of manufacturers capable of supplying special packaging in volume.

By January 1972, 17 firms, including the two research firms, advised FDA that they were developing and testing safety packaging adaptable to mass-production. Also 15 of the firms stated their safety packaging would protect the integrity of the product. FDA concluded that enough safety packages and closures would be available for products to be covered by product standards, except for detergents, and that developing and producing such packages were technically feasible, practical, and appropriate. BPS officials informed us that they believed special packaging would be developed for detergents if required.

Although FDA concluded that enough packages would be available, problems have been encountered, primarily by retail pharmacists, in obtaining enough for certain products. As discussed earlier (see p. 12) FDA has extended the effective dates of standards to January 22, 1973, for certain methyl salicylate, aspirin, and controlled drug products.

POISON CONTROL CENTERS

Such centers provide information to physicians, hospitals, and the public concerning treating and preventing accidental ingestion of poisonous and potentially poisonous substances. Most centers are located in, and funded by,

hospitals, but some are located in, and funded by, municipal health departments. As of June 30, 1972, there were about 580 centers in 49 States (Vermont does not have one), the District of Columbia, and certain territories and possessions.

BPS officials informed us that the States establish and supervise centers. Several States have established centers only in hospitals in more populous cities. Some States, by arrangement or by circumstance, distributed them geographically while others had no criteria for location.

The Surgeon General established a National Clearinghouse for Poison Control Centers in 1957 at the request of the American Public Health Association. The request was made to provide a source of reliable data for the then 16 or 17 centers in operation and to insure that information developed on new products was provided to all centers.

BPS Medical Review and Poison Control Branch administers the clearinghouse. The branch chief informed us that the clearinghouse:

1. Provides information on new products to centers through card files, which list the product; its ingredients, toxicity, symptoms when ingested; and recommended treatment if accidentally ingested.

2. Collects, tabulates, and summarizes poisonings reported by centers.

3. Provides information to the public concerning poison prevention and treatment through events such as Poison Prevention Week.

Centers are requested but not required to report all poisonings to the clearinghouse. In 1971 it received reports of ingestions from about 500 of the approximately 580 centers. A BPS official informed us that the number of centers that report throughout the United States are considered adequate except for two areas, New York City and California.

According to the branch chief, the New York center does not submit reports of ingestions to FDA and only three centers in California do. Two of the California centers are military poison control centers, which normally do not receive

reports of poisonings from the public and thus represent only a small portion of the public. FDA has, on various occasions, tried to obtain reports from New York and additional reports from California; however, as of December 1972, it had not been successful. The branch chief stated that these centers do not report to FDA because of inadequate funds.

The centers' reports generally include information on the patient, the product ingested, symptoms, treatment and results, and circumstances surrounding the poisoning. According to the branch chief, FDA uses the information in the reports to identify products frequently ingested by children under 5 years of age and that for certain products this information has been the basis for establishing special packaging standards. BPS officials stated that the information from centers will be used to monitor the effectiveness of special packages in decreasing the number of accidental ingestions.

Centers, according to the branch chief, are the best sources of information on poisonings because:

1. All types of products are included in the cases reported.

2. The same centers report each year so the information on poisonings is consistent.

3. The data reported by centers represents the largest collection of reports of poisonings available.

NATIONAL ELECTRONIC INJURY SURVEILLANCE SYSTEM

FDA designed NEISS to develop statistically valid, nationally representative accidental injury data for use in identifying product safety problems. NEISS receives daily reports of product-related accidents and injuries, including poisonings, from 119 statistically selected hospital emergency rooms. The data is needed to estimate national incident rates of injuries in various product categories and to provide data on why and how such injuries occurred in order for FDA to initiate corrective actions. Data on each poisoning received by NEISS is forwarded to FDA's National Clearinghouse to supplement reports from poison control centers.

A BPS official informed us that data from centers is better for implementing PPPA than data from NEISS. He stated that the NEISS reports, besides being limited to data collected at 119 hospitals, does not provide sufficiently detailed information on the products ingested and circumstances surrounding the poisonings to be relied on exclusively.

INSTRUCTIONS PROVIDED TO FDA FIELD INSPECTORS

On April 27, 1972, FDA issued general instructions for field inspectors to use during regularly scheduled inspections of firms that manufacture, package, or distribute products subject to special packaging standards.

These instructions contain background information and certain PPPA requirements. The instructions also provide guidelines for inspectors to (1) identify manufacturers who have not complied with the special packaging regulations, (2) determine the cause for the manufacturers' noncompliance, and (3) provide information which will insure proper and effective corrective action. The instructions established a reporting procedure for all inspections, inquiries, regulatory actions, or requests for information concerning PPPA.

On August 8, 1972, FDA issued additional instructions for inspectors assigned to inspect pharmacies to determine their compliance with PPPA. The instructions emphasize efforts to obtain voluntary compliance by pharmacies. If these efforts fail FDA may refer the violative pharmacy to a State Board of Pharmacy for appropriate action or initiate injunction proceedings or prosecution.

As of December 1, 1972, FDA issued instructions for enforcing special packaging standards for aspirin, furniture polish, methyl salicylate, and controlled drugs. FDA plans to issue inspection instructions on each new standard.

MEMBERS OF THE TECHNICAL ADVISORY COMMITTEE, THEIR AFFILIATIONS AND TERMS OF APPOINTMENT, AND NUMBER OF MEETINGS THEY ATTENDED

	Term of appointment From	Term of appointment To	Meetings attended
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE:			
Dr. Arthur J. Lesser (note a)	Apr. 1971	June 1974	1 of 5
Dr. Sarah H. Knutti	July 1972	June 1975	2 of 2
DEPARTMENT OF COMMERCE:			
Michael F. Butler	Apr. 1971	Indefinite	3 of 7
Dr. W. Wayne Meinke (note b)	Apr. 1971	Indefinite	1 of 1
Ralph E. Schofer	July 1972	Indefinite	2 of 2
MANUFACTURERS OF HOUSEHOLD SUBSTANCES SUBJECT TO PPPA:			
Alfred A. Mulliken	Apr. 1971	June 1972	5 of 5
John T. Thielke	Apr. 1971	June 1973	7 of 7
Charles H. Hagen	Apr. 1971	June 1974	6 of 7
SCIENTISTS WITH EXPERTISE RELATED TO PPPA AND LICENSED PRACTITIONERS IN THE MEDICAL FIELD:			
Dr. Robert H. A. Haslam	Apr. 1971	June 1972	5 of 5
Dr. Myron S. Weinberg	Apr. 1971	June 1972	3 of 5
Dr. Robert G. Scherz	Apr. 1971	June 1973	6 of 7
Dr. Ned W. Smull	Apr. 1971	June 1973	7 of 7
Dr. Walter M. Booker	Apr. 1971	June 1974	6 of 7
Dr. Matilda S. McIntire	July 1972	June 1975	1 of 2

APPENDIX I

	Term of appointment				Meetings attended
	From		To		
CONSUMERS:					
Richard Slade	Apr.	1971	June	1972	5 of 5
Dr. Donald E. Hayhurst (chairman)	Apr.	1971	June	1973	7 of 7
Bernice Johnson (note c)	Apr.	1971	June	1974	0 of 5
Maryjane Morgan	Apr.	1971	June	1974	7 of 7
Dr. Mary Purchase	July	1972	June	1975	2 of 2
Patricia T. Van Betten	July	1972	June	1975	2 of 2
Lupe Ortiz	Nov.	1972	June	1975	0 of 0
MANUFACTURERS OF PACKAGES AND CLOSURES FOR HOUSEHOLD SUBSTANCES:					
John D. Northup	Apr.	1971	June	1972	5 of 5
Peter P. Gach	Apr.	1971	June	1973	7 of 7
Gerald L. Roy	Apr.	1971	June	1974	6 of 7
Charles B. Sanders	July	1972	June	1975	2 of 2

[a]Resigned as of June 30, 1972.

[b]Resigned as of August 16, 1971.

[c]Removed by the Commissioner, FDA, as of June 30, 1972.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

FEB 27 1973

Mr. Morton A. Myers
Assistant Director
Manpower and Welfare Division
U.S. General Accounting Office
Washington, D.C. 20548

Dear Mr. Myers:

As requested in your letter of January 26, we reviewed your draft audit report entitled, "Implementation of the Poison Prevention Packaging Act of 1970." The report, in our opinion, fairly presents the efforts made -- and the obstacles faced -- by the Food and Drug Administration of this Department in carrying out the intent of this most critical piece of legislation. In developing the final version of this report, you may wish to consider some comments made on certain technical aspects of this report, which are enclosed with this letter.

We appreciate the opportunity to comment on this report before it is released in final form.

Sincerely yours,

James B. Cardwell
Assistant Secretary, Comptroller

Enclosure

GAO note: The technical comments referred to have been deleted as they pertained to material in the draft report which has been revised.