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September 1, 1971

All Members of the SPI Food,
Drug and Cosmetic Packaging
Materials Committee

Re: FDA Proposed Rule Making to
Require Child Protection
Packaging Standards for
Preparations Containing
Aspirin

Gentlemen:

As you will recall, we have been keeping you informed, from time to time, relative to developments in connection with the Poison Prevention Packaging Act of 1970. Further in this regard we are enclosing herewith a reproduction of page 17512 from the September 1, 1971, Federal Register. As you will note, the Food and Drug Administration has now determined that special packaging, in accordance with the Act, should be required to protect children from ingesting aspirin or preparations containing aspirin.

Provision is made for interested persons wishing to file comments to do so within thirty days after publication of this Notice. We would appreciate any comments or instructions members of the Food, Drug and Cosmetic Packaging Materials Committee, or the Food and Drug Bottling Committee of the Plastics Bottle Division might care to give us concerning this proposal. We would anticipate that the manufacturers of the aspirin products would have a more direct interest in commenting in this connection; however, should the members care to submit recommendations concerning this proposal, please notify us within the next fifteen days, and we shall follow up appropriately.

Cordially yours,

Jerome H Heckman

Enclosure

Proposed Rule Making

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 295]

CHILD PROTECTION PACKAGING STANDARDS FOR PREPARATIONS CONTAINING ASPIRIN

Proposed Rule Making

Through investigations by the Food and Drug Administration and from other available information, the Commissioner of Food and Drugs has determined that the ingestion of aspirin and preparations containing significant amounts of aspirin have been a leading cause of fatalities and hospitalizations of children under 5 years of age.

A review of a 2½-year compilation (Jan. 1968–June 1970) of Poison Control Center reports received by the National Clearinghouse for Poison Control Centers reveals the following regarding children under 5 years of age:

1. Aspirin is the item most frequently ingested accidentally.

2. Aspirin is the leading cause of hospitalizations due to accidental poisonings.

3. The dosage size of aspirin that is most frequently ingested accidentally and that is the leading cause of hospitalizations is 1¼ grains.

4. Five-grain aspirin is the fourth most frequently ingested accidentally and the sixth leading cause of hospitalizations.

5. Products containing aspirin in combination with other ingredients have upon accidental ingestion caused fatalities and hospitalizations.

The medical community has long been concerned with aspirin poisoning in children. This inspired two FDA conferences; namely, 1958 Conference on Salicylate Poisoning and 1966 Conference on Prevention of Accidental Ingestion of Salicylate Products. The first resulted in a warning label and the second in limiting 1¼-grain aspirin tablets to 36 per container. The 1966 conference also concluded that child-resistant safety closures were desirable for packaging 1¼-grain aspirin tablets and established a subcommittee on safety closures to develop methods for evaluating these closures. The subcommittee's report specifying closure testing methodology was submitted to the Commissioner on December 7, 1970.

After review of the aforementioned information and consultation, pursuant to section 3, with the technical advisory committee convened in accordance with section 6 of the Poison Prevention Packaging Act of 1970, the Commissioner finds that the nature of the hazard to children posed by aspirin and preparations containing significant amounts of aspirin, by reason of their availability and 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 substances. Furthermore, the Commissioner finds that the special packaging to be required is technically feasible, practicable and appropriate for such substances.

Accordingly, pursuant to provisions of said act (secs. 2(4), 3, 5, 84 Stat. 1670–72; 15 U.S.C. 1471–74), and under authority delegated to him (36 F.R. 11770) the Commissioner proposes to add to Part 295—Regulations Under the Poison Prevention Packaging Act of 1970 (36 F.R. 13335), two new sections as follows (other portions of these sections regarding other substances are being proposed in separate documents):

§ 295.2 Substances requiring "special packaging."

(a) The Commissioner has determined that special packaging within the meaning of section 2(4) of the act and as specified in this part is required to protect children from serious personal injury or serious illness and that such packaging is feasible, practicable, and appropriate for the following substances:

(1) Prescription or nonprescription capsules, tablets, and/or other preparations containing aspirin (including "baby aspirin") shall be packaged in accordance with the provisions of § 295.3(a)(1).

(b) None of the substances listed under any subparagraph of paragraph (a) of this section shall be distributed in a noncomplying package under the exemption provided in section 4(a) of the act unless the manufacturer or packer first provides the Commissioner of Food and Drugs with a sample of such intended noncomplying package. A sample of each size package of each substance which a manufacturer or packer distributes in "special packaging" shall also be submitted. Sample packages should be sent to: Food and Drug Administration, Attention: Bureau of Product Safety, 200 C Street SW., Washington, D.C. 20204.

§ 295.3 Poison prevention packaging standards.

(a) To protect children from serious personal injury or serious illness resulting from handling, using, or ingesting household substances, the Commissioner has determined that packaging designed and constructed to meet the following standards shall be regarded as "special packaging" within the meaning of section 2(4) of the act. Specific application of these standards to substances requiring special packaging is in accordance with § 295.2.

(1) Special packaging which when tested by the method described in § 295.10 of this part meets the following specifications:

(i) Child-resistant effectiveness not less than 85 percent without a demonstration and not less than 80 percent after a demonstration of the proper means of opening such special packaging.

(ii) Adult-use effectiveness not less than 90 percent.

Interested persons may, within 30 days after publication hereof in the FEDERAL REGISTER, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-62, 5600 Fishers Lane, Rockville, Md. 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during regular business hours, Monday through Friday.

Dated: August 27, 1971.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc.71-12781 Filed 8-31-71;8:49 am]

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[14 CFR Part 39]

[Docket No. 11354]

BRITTEN NORMAN MODELS BN-2 AND BN-2A AIRPLANES

Proposed Airworthiness Directives

The Federal Aviation Administration is considering amending Part 39 of the Federal Aviation Regulations by adding an airworthiness directive applicable to Britten Norman Models BN-2 and BN-2A airplanes. There have been reports of loose Jo-Bolts in the engine frame mounting brackets attached to the wing front spar on models BN-2 and BN-2A airplanes that could result in failure of the engine frame mounting brackets attachments. Since this condition is likely to exist or develop in other airplanes of the same type design, the proposed airworthiness directive would require periodic inspection of the six Jo-Bolts securing each of the two upper engine mounting frame brackets of each engine mounting frame to the wing front spar for security of attachment. Loose Jo-Bolts would have to be further inspected for integrity of locking between the bolt and nut. The directive would also require replacement, with improved attachment bolts in accordance with Britten Norman Modification NB/M/455, of the 12 Jo-Bolts of an engine mounting frame on which the locking between any Jo-Bolt