133

ADVISORY OPINION

3 0 SEP 1974

6(b) CLEARED:
No Mfrs Identified
✓ Excepted general
Mfrs Notified
Comments Processed
lah 6/21/84

Dr. Bertha Iturrioz Arteche
Vice President
Scientific Affairs
Reid-Provident Laboratories, Inc.
25 Fifth Street, N. W.
Atlanta, Georgia 30308

Dear Dr. Arteche:

This is in response to your letter of August 23, 1974, inquiring whether a manufacturer's bottle containing 100 capsules or tablets of an oral antibiotic need be contained in child-resistant packaging when supplied to a pharmacist.

As stated during your telephone conversation with Mr. Stephen Lemberg, the primary responsibility under the Poison Prevention Packaging Act for complying with the child-resistant packaging standards for human prescription drugs rests with the individual dispensing such drugs at the consumer level rather than upon the manufacturer. Where, however, the manufacturer packages a prescription drug in a package which he intends, or which is customarily used, in dispensing the drug to the consumer, the manufacturer also has the responsibility for placing that drug in child-resistant packaging. Therefore, a bulk package for pharmacy use containing 100 capsules or tablets of an oral antibiotic which is rarely, if ever, prescribed in amounts that high, need not be placed in child-resistant packaging by the manufacturer.

Please note that the position stated herein is an advisory opinion for the guidance of industry and other interested persons. Should future experience show that this position is not consistent with the Commission's responsibilities under the Poison Prevention Packaging Act, the position may be changed accordingly.

Sincerely,

Original signed by
Michael A. Brown
Michael A. Brown
General Counsel

ADVISORY OPINION

RECEIVED
SEP 4 1974
Consumer Product
Safety Commission
Office of the
General Counsel

REID-PROVIDENT LABORATORIES INC.
25 FIFTH STREET, N.W./ATLANTA, GEORGIA 30308

August 28, 1974

Mr. Steven Lenberg
Attorney
Consumer Products Safety Commission
Washington, D. C. 20207

Dear Mr. Lenberg:

This is to confirm our telephone conversation in connection with the usage of the child-resistant closure on bottles of 100 antibiotic capsules or tablets.

I specifically mentioned Erythromycin, Ampicillin and Tetracycline because it is my opinion that since these antibiotics may cause serious side effects mostly when they are used over a long period of time, physicians very seldom, if any, prescribe them in bottles of 100's. They rather prescribe them in quantities not exceeding more than 10 days of medication which could be at the most, from 40 to 50 dosages. Moreover, they probably prescribe them in bottles of 30's, with the indication that the prescription can be refilled one or more times.

I understood you mentioned that the interpretation of your department in cases as explained above (antibiotics), was to consider it as a bulk package in which the bottle will not require the child-resistant closure because the pharmacist will transfer the tablets to another bottle and put his label on it.

As we discussed on the telephone, the label of the drug should bear the cautionary legend as not to be dispensed without prescription and also the product should be accompanied by the official monograph. Also, I interpreted from our conversation, that the manufacturer is required to use the child-resistant closure on those prescription drugs which will be dispensed in the original containers. That is, the package is intended to go directly to the consumer.

Mr. Lenberg, I would appreciate very much if you would confirm with a letter whether or not my interpretation was correct on the matter that we discussed over the phone concerning antibiotic products.

Sineerely,

REID-PROVIDENT LABORATORIES, INC.

Bertha I. Arteche

Dr. Bertha Iturrioz Arteche
Vice President
Scientific Affairs

BIA/ms