HOFFMANN-LA ROCHE INC.

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December 18, 1973

Hearing Clerk
Food and Drug Administration
Department of Health, Education and Welfare
Room 6-88
5600 Fishers Lane
Rockville, Maryland 20852

Re: Proposal by FDA to Restrict the Use of Talc in Food and Drugs on the Basis of Asbestos Content
38 FR 27076, September 28, 1973

Gentlemen:

Concerning the captioned proposal, Hoffmann-La Roche Inc. has the following comments.

Hoffmann-La Roche Inc. is a New Jersey corporation engaged in, among other things, the development, production and sale of various pharmaceutical products. Certain of these products contain talc as an ingredient. In this connection, we are interested in the proposed restrictions of the use of talc in food and drugs on the basis of asbestos content appearing in the Federal Register of September 28, 1973.

Our comments are directed toward the specific test procedure set forth in proposed Section 121.2006(c)(2). After an intensive study of this area, we believe that this proposed test is not as accurate as is desirable and reasonably practicable in terms of differentiating asbestos from talc or other mineral substances commonly found in talc. Additionally, the test is unnecessarily time consuming.

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To meet these drawbacks, a somewhat modified test has been developed and is set forth in Attachment A. This modified test appears both more accurate and more efficient than that contained in the original Federal Register proposal. The modified test is not wholly satisfactory, however, because like the proposed test, it fails to differentiate asbestos from certain minerals frequently encountered in talc. Hence, this modified test, like the proposed test, will, if implemented, result in some erroneous rejections. It is therefore recommended that the modified test be adopted by FDA in place of the proposed Section 121.2006(c)(2) as part of the standard under which talc should be examined for asbestos content; but that implementation of this regulation be stayed until July 1, 1974 so that supplementary tests as described below may be explored.

The modified test is important because under FDA's proposed method of testing for chrysotile fibers and amphiboles, it is often difficult in practice to spot the presence of chrysotile fibers. The modified test utilizes a larger differential in the indices of refraction of chrysotile and the index liquid, which substantially facilitates visualization of the chrysotile. The change significantly increases the accuracy of the test. The modified test does not result in any loss of accuracy in testing for amphibole content.

In certain unusual instances, there is a possibility that the modified test will count talc particles as chrysotile. An additional specific test, adapted from one aspect of the proposed Section 121.2006(c)(2), is included in the modified test to allow for this contingency and hence prevent erroneous rejections. This additional test would need be used only rarely.

The modified test, as opposed to the proposed test, results in practice in a reduction of test time from approximately thirteen days to about three days.

The modified test is not fully acceptable by itself, however. There is a group of several minerals commonly found in talc which, under either the proposal or the modified test, will yield a positive test for

either chrysotile or amphiboles even though these substances are absent. We have tentatively identified these minerals as chlorite, kaolinite, and epidote, although there may be additional similar non-asbestos minerals within this group. Kaolinite interferes with the optical test for chrysotile, and chlorite and epidote interfere with the optical test for amphiboles. Details on refractive data for chlorite, kaolinite, and epidote, and background data from Bureau of Mines publications indicating the existence of such minerals in talc, are for your ready reference contained in Attachment B.

Because the proposed modified test is not fully satisfactory, we presently plan to investigate use of differential scanning calorimetry, infra-red spectroscopy, and X-ray diffraction to differentiate asbestos from the non-asbestos minerals noted and trust we will have further information available at an early date.

On the basis of the foregoing reasons, we are very concerned that implementation of the proposal, in either its original Federal Register form or in the suggested improved modified form in Attachment A, could, by resulting in erroneous rejections of talc caused by mistaking the above minerals for asbestos, lead to critical difficulties in obtaining usable talc supplies. Accordingly, we strongly recommend that any implementation of the regulations in either the proposed or modified form be stayed at least until July 1, 1974 so that alternate supplemental testing methods may be explored.

Respectfully submitted,

HOFFMANN-LA ROCHE INC.

E. B. Anderson
Vice President

EBA: Wbp
Attachments

Submitted in quintuplicate