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RJR

Scientific Affairs Division

Interoffice Memorandum

TO: C. A. Blixt

FROM: Dr. D. Cooper Rees

DATE: May 31, 1991

SUBJECT: Use of "Woodpulp"

The purpose of this memorandum is to document Scientific Affair's involvement in issues regarding use of "woodpulp" in product, and solicit your opinion and advice concerning these issues.

[note: The term "woodpulp" is used in this memo for convenience only. Our review of the literature, regulations, and discussions with suppliers indicate that "pulp" may be the more appropriate label].

CHRONOLOGY OF SCIENTIFIC AFFAIRS INVOLVEMENT

Scientific Affairs (SA) was approached in the Spring of 1991 regarding the use of "woodpulp" in subgeneric products by Joe Inman and the use of "woodpulp" as a cigarette innerwrap in Project XA. Joe's primary interest was with respect to choice of types of "woodpulp", specifically, was there any information that Scientific Affairs could provide which would aid in the selection of "woodpulp". The "woodpulp" used in XA innerwrap is the same type used in cigarette papers.

Shortly after this meeting, D. Cooper Rees attended weekly meetings with Mary Stowe and others to develop information to evaluate the inclusion of "woodpulp" into G7 sheet. From the beginning of the project, it was implied that "woodpulp" would be sold in product nationally by July 1991. Scientific Affairs noted from the very beginning that given the use level of "woodpulp" (expected to be within the top 10 RJR ingredients used) testing would be recommended by Scientific Affairs which could not be generated within the given timeframe. Since the decision had apparently already been made to use "woodpulp, Scientific Affairs developed a testing strategy designed to provide limited information within

the time frame specified. In addition, Scientific Affairs suggested that following the initial testing plan a more complete testing plan be undertaken to provide the level of information typically required with respect to ingredients used at levels greater than 0.5%. The testing plans, both pre- and post- July were presented to Dr. Di Marco near the end of April, 1991. Attached is a copy of the presentation.

ADDITIONAL CONSIDERATIONS RELEVANT TO THE CURRENT TESTING STRATEGY

Given the intended use level, "woodpulp" may easily fall into the top 10 ingredients used by RJR. As has been noted for other relatively high level ingredients (e.g. glycerol, licorice, propylene glycol, cocoa; see presentation by D.C. Rees of 12/03/90) a substantial amount of biological testing data exists to support the level of human exposure from a toxicological standpoint. Limited biological data are available to support the use level of "woodpulp" in cigarettes. While the testing plan designed to address toxicological issues for the July deadline is reasonable, it does not include measures of other end points such as carcinogenicity and respiratory tract effects.

These end points have been examined for other high volume ingredients. Lack of such data poses a number of issues. For example, in regards to use of "woodpulp" what would be the implication of finding positive results on either or both of these studies? from a toxicological/regulatory perspective? from a product liability perspective?

To date, RJR has undertaken a policy of requiring "adequate" information to assess and support human exposure to ingredients. A recent example, levulinic acid for Project XB, illustrates the point. Scientific Affairs designed a program which would permit an evaluation of the effects of levulinic acid in products. Results of these tests would be available before national roll-out. Another relatively high level ingredient is diammonium phosphate. Although RJR has not developed all the information "in-house", there is evidence available to justify and support its current use. Thus, the approach being taken for "woodpulp" is inconsistent with previous strategies to evaluate use of ingredients at similar inclusion levels. Attached is a table which presents an overview of the types of data available for several ingredients.

In summary, previous undertakings by RJR regarding use of relatively high volume ingredients have required adequate biological testing prior to large scale production. Adequate biological testing has typically been defined as at least an inhalation study and, in general, a skin painting study for ingredients used above a level of 0.5% in products. The approach being proposed for "woodpulp" is, therefore, inconsistent with previous RJR policy. While there is no evidence to suggest that use of "woodpulp" would put consumers at risk, the data available from which to draw such a conclusion are limited.

I would appreciate your reviewing these issues and providing us with your legal advice concerning the issues we have identified, as well as any others you foresee.

DAR

Attachments

cc: Dr. A. W. Hayes
Dr. R. L. Suber