December 30, 1985

H. W. Dietz

Subject: Activities Report for December, 1985

1. Carbopol

We have received the proposed NF Monographs for Carbomers, 910, 934,940 and 941 from the U.S.P. Rather than a family monograph as U.S.P. had proposed, there will be separate monographs for each Carbomer. The monographs are acceptable to us as written and we have so informed U.S.P. They will not address residual acrylic acid or volatile organics at this time.

Before publication, they must be reviewed by the U.S.P. Revision Committee and be proposed in the Pharmacopeial Forum.

2. Goodrite 3125

I have received the data requested by the FDA for our Goodrite 3125 petition from the Brecksville Environmental Lab. The detection limit for G.R. 3125 in aqueous extracts now appears to be higher than originally assumed. The net effect is a rise in the estimated daily intake of G.R. 3125 by about 0.15 mg per day. This slight increase may lead to some further use restrictions by the FDA. The results will be submitted to the FDA with a copy to Ciba-Geigy.

3. Estanes

The Institut de Biopharmacie Rhône-Poulenc (France) is developing a transdermal dosage form utilizing Estane 5702. Under the terms of a secrecy agreement, we have sent to Rhône-Poulenc copies of our original polyurethane food additive petition, U.S.P. Class VI tests and other relevant tests and data from our FDA Estane Drug Masterfile.

4. Toxicology conference

I attended a Managing,Conduct and Data Quality of Toxicological Studies Conference sponsored by the government and industry, Nov. 18-20 in Raleigh, N.C. The conference addressed current concepts and strategies to improve the quality of toxicological studies. A number of quality assurance programs utilized by government and industry were discussed including management, pre-study conduct, pathology, regulatory and international aspects. The conference was very informative and productive. There were over 600 attendees from government, industry and academia.

5. SPI Food, Drug and Cosmetic Packaging Materials Committee

On December 3-4, I attended the SPI-FDCPMC meeting in Orlando, Fla. Updates on food safety legislation and regulation, PVC, and other current FDA, EPA and OSHA activities were discussed.

The "Third Party" task force held its first meeting. The purpose of this task force is to study the perceived need of a third party to review and certify the status of ingredients as to their GRAS, no migration status. This would be an effort to avoid the long delays experienced with the FDA in such situations. A questionnaire was developed and will be sent to various companies and organizations to determine the need for an independent third party review. In light of FDA's recent "Threshold of Regulation" proposals, we decided not to take more substantive action at this time.

6. Institute for Polyacrylate Absorbents

The first annual meeting of the Institute for Polyacrylate Absorbents was held on Dec. 17 in Crystal City, Virginia. The purpose of this organization is to address the scientific and regulatory issues which may impact upon the health, safety and environmental aspects of fluid absorbing polyacrylates. BFG proposes to join the institute as an affiliate (non-voting) member. In addition to organizational matters, the chemistry and toxicology of polyacrylate absorbents were discussed. John Moore, Assistant EPA Administrator for Pesticides and Toxic Substances spoke on the EPA concerns relating to acrylates under TSCA.

7. PVC

The FDA is reportedly ready to publish the long-awaited PVC regulation. The regulation will limit the RVCM. The proposed RVCM limits are dependent on the application and range from 5 ppb in flexibles, gaskets, coatings, 10 ppb in rigid sheet to 50 ppb PVC water pipe.

8. Threshold of Regulation

Meetings have taken place between the FDA and industry regarding a "threshold of regulation" concept in relation to FDA's 1985 Action Plan. The proposals presented would involve a three-track system for substances used in food packaging materials. The system would apply a threshold of regulation for some substances, a "fast-track" approval for others and normal food additive petitions for others. Toxicology, the intended use, and either the level of migration or level of detection would be considered in setting the threshold value of a substance.

Such a system could save considerable time and money in the development of food contact materials.

9. Methylene Chloride

For the first time, the FDA has used the "de minimis" concept for a direct food additive. The FDA has taken a major step toward applying the rule of reason to the interpretation of the Delaney Clause. The Agency has advised it will take no action against the continued use of methylene chloride as a solvent to decaffinate coffee, even though there is some residue in the coffee. Relying on the Monsanto Case, the FDA concluded that the level of methylene chloride residue in the coffee poses an upper bound risk of less than 1×10^{-6} and has ruled that a risk of this magnitude will be deemed de minimis so that the Delaney Clause ban concept need not be applied.

Should this decision stand up in court, it could have a tremendous effect on packaging material migrants, i.e. indirect additives.

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