

JOSEPH E. KELLER
JEROME B. HECKMAN
CHARLES M. MEEHAN
WILLIAM H. BORGHESEANI, JR.
ROBERT E. TIERNAN
WAYNE V. BLACK
DAVID L. HILL
MARTIN W. BERCOVICI
PETER M. NEMKOV
JOSEPH E. HADLEY
CAROLE C. HARRIS
PETER THOMAS SMITH
MICHAEL P. MORRONE
LARRY S. SOLOMON

LAW OFFICES
KELLER AND HECKMAN
450 17TH STREET, N.W.
SUITE 1000
WASHINGTON, D.C. 20036

TELEPHONE
202 296-2700
CABLE ADDRESS "KELMAN"

July 26, 1976

No. 23

TO: All Members of PVC/VCM Mailing List

Ladies and Gentlemen:

Although there is actually little in the way of "hard" news to report at this time, we felt it might be helpful if we wrote to touch on some of the administrative activities which we understand are going on at the Food and Drug Administration (FDA) in connection with the FDA proposal on vinyl chloride monomer and polyvinyl chloride (PVC) plastics, as well as to provide information which we have received from our associate counsel on the Environmental Protection Agency (EPA) schedule for its vinyl chloride emission standard.

FDA

The major FDA-related activity with which we have been concerned revolves around the jurisdictional question about potable water in general, and PVC piping systems for potable water in particular. We have previously reported that a Joint FDA/EPA Task Force has been considering a broad spectrum of problems relative to overlapping jurisdiction between the two agencies. The discussions of the inter-agency Task Force are understood to include what to do about direct additives for water treatment purposes, and process water in food processing plants, as well as indirect additives which might become a component of potable water as a result of contact with piping systems and other water handling equipment.

We gather that the negotiations have now reached a point where a draft Memorandum of Understanding is being prepared for discussion and revision within and between

SPI-24329

July 26, 1976
Page Two

the two agencies. Although we have not seen a copy of this draft (indeed, we understand it may not yet have been completed) our contacts lead us to believe that it is likely to look towards a renewal of the former program whereby EPA recommended to the various States equipment, chemicals and the like which EPA found to be suitable for water treatment and handling. In reaching decisions as to suitability, however, it is possible that the memorandum will provide that EPA will not recommend any substance which is reasonably expected to become a component of water under the intended conditions of use unless the substance is the subject of an applicable Food Additive Regulation, generally recognized as safe (GRAS), or prior-sanctioned.

If the final agreement between the two agencies follows this pattern, piping systems can be manufactured using components which are GRAS, prior-sanctioned, the subject of Food Additive Regulations, or which may not reasonably be expected to become components of water under the intended conditions of use. With respect to this latter determination, we understand that EPA will reactivate its Cincinnati facilities so that it can confirm such judgments independently.

It is our best judgment (confirmed by FDA and EPA contacts) that no final resolution of the FDA/EPA jurisdictional question is likely before September; consequently, it is unlikely that any final drafts of FDA Regulations on PVC can be prepared before that time. It would appear our earlier estimate that no regulations should be expected before the middle of September is still well founded.

By the time you receive this letter, many of you may have already learned through the general press that FDA Commissioner Schmidt will resign at the end of this year. What the long range effect of this decision will be we cannot speculate. We have a modest hope, however, that Dr. Schmidt's decision to remove himself from the gladiator's arena may make it possible for him to reach a decision on the PVC regulatory question solely on the

SPI-24330

July 26, 1976
Page Three

basis of his best scientific judgment and without regard to public relations concerns. In any event, hopefully, we shall learn more about the direction FDA will go in connection with the PVC rulemaking as the end of summer approaches.

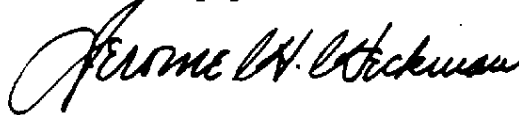
EPA

As we have often done in the past, we are attaching a report received from our associate counsel, Ruckelshaus, Beveridge, Fairbanks & Diamond. This letter, dated July 16, 1976 provides a review of EPA's anticipated schedule with respect to the Standard for vinyl chloride emissions. Based upon the information available, associate counsel believes that the EPA Standard for vinyl chloride emissions may be promulgated sometime in October.

• * •

We hope you will find this letter helpful in following the progress of the FDA and EPA final Regulations. As you know, we have been maintaining the closest possible contact with the two agencies and will continue to inform you promptly as we learn anything of substance.

Cordially yours,



Enclosure

SPI-24331