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May 22, 1973

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TO: SPI Food, Drug and Cosmetics
Packaging Materials Committee

SPI Plastic Bottle Division

RE: "Requirement of Environmental
Impact Analysis Reports for
Plastic Bottles for Food Use."

Gentlemen:

Via some of our sources here in Washington, we have just received the enclosed draft of a "Notice to Manufacturers and Distributors" which we have been advised by the Office of the General Counsel of the Food and Drug Administration will be published in the Federal Register in the very near future, possibly within the next two or three days, but probably not until a little later. To a degree, I would say that FDA's plan to issue this Notice comes as a bit of a shock, following so closely on the heels of all of its activity relative to our PVC liquor bottles problem. On the other hand, I think we have to say that we have been anticipating some type of action of this type since Peter Hutt has indicated to us on a number of occasions in recent months that the Food and Drug Administration would be considering the requiring of environmental impact statement activity relative to all plastic bottles.

I do want to caution you that what we are sending is nothing more than a draft at this moment since there has been no publication in the Federal Register. I have already, however, spoken at some length with FDA's General Counsel, Mr. Hutt, about the matter and he has confirmed that the draft enclosed is substantially what will appear in the Federal Register. Among other things, he has informed me that he believes the Food and Drug Administration has the duty under the National Environmental Policy Act of 1969 to evaluate all packaging materials from an environmental point of view. Thus, his position is that the plastic bottle

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inquiry will be in the nature of a pilot effort and other packages, including glass, paper, etc. may ultimately have to come under the same type of scrutiny.

One point I might mention is that I strongly suggested to Mr. Hutt that the 90 day period provided for in the draft Notice is wholly unrealistic. He indicated that, on the basis of my comment, he would give further consideration to this point at least and might revise the Notice to provide more time. I do want to make it clear that Mr. Hutt's present thinking is that NEPA has imposed upon FDA a very unwelcome duty to conduct these types of evaluations even on such well established bottle polymers as polyethylene, polypropylene, and all additives used in connection with any polymer that might be employed to manufacture bottles for food use. The Food and Drug Administration is by no means happy with this situation, the thought having been expressed to me that it believes NEPA has in many ways amended the Federal Food, Drug and Cosmetic Act beyond anyone's wildest dreams. It nevertheless feels that it must proceed along these lines as a matter of statutory duty unless and until something is done to delimit the statutory effect of NEPA.

About the only thing I can say is that if and when publication of this Notice takes place, some sort of major effort will be required of a number of companies, if not the industry as a whole. As of this writing, we have not had enough of an opportunity to think the matter through so as to be able to suggest a coherent way in which to handle the problem.

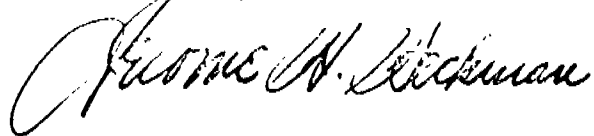
It may be that more light will be cast on the matter during Peter Hutt's appearance at our Food, Drug and Cosmetic Packaging Materials Committee meeting on May 31 but this remains to be seen. He has promised to be prepared to try to tell us more about the Food and Drug Administration's position at that time.

In the meantime, we thought it would be best to give you this advance notice so that you can be thinking about the problem along with us. All I can add at this

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point is that it looks to me as if the Food and Drug Administration is going to make certain that we have a "long, hot summer."

Cordially yours,

A handwritten signature in cursive script, reading "Jerome W. Wickman". The signature is written in dark ink and is positioned below the typed name.

Enclosure

[Retyped from original draft received from Food and Drug Administration.]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
FOOD AND DRUG ADMINISTRATION
NOTICE TO MANUFACTURERS AND DISTRIBUTORS
REQUIREMENT OF ENVIRONMENTAL IMPACT ANALYSIS REPORTS
FOR PLASTIC BOTTLES FOR FOOD USE

Major Federal actions significantly affecting the quality of the human environment require an environmental impact statement pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969 (NEPA). Several food additive regulations have been issued for a number of plastic substances intended for fabrication into bottles for use as food containers. The Food and Drug Administration has also given advisory opinions to inquirers that certain plastic substances fabricated into bottles are not food additives under the conditions of their intended use.

The Commissioner of Food and Drugs recognizes the need for issuance of an environmental impact statement concerning plastic bottles for food use. Full consideration in this statement will be given to the environmental issues relevant to FDA approvals by regulation for and other agency actions taken on plastic substances suitable for use in fabricating such bottles. Section 6.1(e) of FDA's procedures for preparation of environmental impact statements (38 FR 7001) provides that applications or petitions submitted on or after March 15, 1973, requesting action by the agency shall include an environmental impact analysis report. In order to consider prior actions as well as current proposals, petitioners for food additive regulations and recipients of advisory opinions issued prior to March 15, 1973, for plastic substances used or intended for use in the fabrication of bottles for food use are hereby notified that they are required to submit by (90 days from the date of publication in the FEDERAL REGISTER) an environmental impact analysis report containing the information prescribed by 21 CFR 6.1(g) and 21 CFR 121.51(c)(II).

The Food and Drug Administration at this time is limiting the requirement for environmental impact analysis reports to those plastic substances suitable for fabrication

of such bottles. Should it become evident that other forms of food packaging materials authorized prior to March 15, 1973, could have a significant impact on the quality of the human environment, the necessity of submitting environmental impact analysis reports for such other forms of food packaging will be announced by publication in the FEDERAL REGISTER.

This notice is issued pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1042, 1055, 72 Stat. 1784-1788, as amended; 21 U.S.C. 321(s), 348, 371(a)) and the National Environmental Policy Act (42 U.S.C. 4332 (2)(C)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: _____
