


PFIZER INC., 235 EAST 42nd STREET, NEW YORK, N. Y. 10017

CHARLES F. HAGAN
Assistant General Counsel

August 22, 1972

Messrs. M. Hoover
G. W. Ingle
W. A. Knapp ✓
W. H. Meyer
R. M. Miller

Re: FDA's Proposed "Environmental" Impact Regulations

Gentlemen:

As I mentioned at our meeting on August 17, I will be away on vacation from tomorrow through September 6. Therefore, I am sending to you with this letter a very hastily drawn set of proposed comments on the above proposed rule-making. Much can be done to improve these comments, but I wanted to get the draft out to you to be sure that there is agreement on the position that the Association should take.

While I am away, I am sure Morgan will be in touch with each of you to obtain your thoughts.

Sincerely yours,



Charles F. Hagan

CFH:mm
Attachment

cc: Mr. Taylor W. Hanavan

AUG 25 1972

ASI 00002862

DRAFT

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

Dear Sir:

The Manufacturing Chemists Association (MCA) sets forth herein its comments on the proposed "Environmental Impact Statements" regulations, which were published in the FEDERAL REGISTER for July 12, 1972, 37 F.R. 13636-13640.

MCA is a nonprofit trade association of 165 United States company members representing more than 90% of the production capacity of basic industrial chemicals within this country. Many of these companies produce products subject to the jurisdiction of FDA, such as food chemicals and color additives. They therefore have submitted, and will continue to submit, a variety of information and data to FDA of the kinds that are dealt with in these proposed regulations.

GENERAL REMARKS

In order to set the stage for the more detailed comments which follow, we would like to make two general comments on the subject matter of this proposal.

First, the requirement under Section 102(2)(C) of the National Environmental Policy Act of 1969 for government agencies to prepare a detailed statement of environmental impact applies only to (i) proposals for legislation, and (ii) "other major Federal actions significantly affecting the quality of the human environment". (Underlining added). We submit there will be very few occasions when the type of matters which are the subject of this proposal would ever rise to the level of constituting a "major" Federal action "significantly" affecting the environment. Therefore, we would urge that this proposal in its totality far exceeds any reasonable interpretation of the scope of the obligation which Congress intended to impose on an agency such as the Food and Drug Administration.

Second, there is nothing in the National Environmental Policy Act, nor in the Food, Drug and Cosmetic Act, that authorizes the portions of this proposal that deal with the affected industries.

Congress in 1969 required government agencies to consider the environmental impact of their actions, and required the preparation of environmental impact statements, but Congress did not amend the Food, Drug and Cosmetic Act, or pass any legislation which imposed on industry the type of requirements that FDA proposes in this proposed rule-making.

We do not intend our comments to express a lack of willingness to cooperate with the Food and Drug Administration on the rare occasion when an action contemplated by it meets the statutory test described above, which necessitates that the agency prepare an environmental impact statement. Undoubtedly, whenever such situation should arise, the affected company or industry would be pleased to cooperate with Food and Drug to assist it to perform its responsibilities under the National Environmental Policy Act.

DETAILED COMMENTS

Proposed Section 6.1. Subparagraphs (2) (3) (4) and (5) of subsection (b) and subsection (f) would require submission by a manufacturer of an environmental impact analysis report, covering destruction of articles recalled, condemned, etc. It is inconceivable to us that such destruction would ever amount to the type of major action requiring the preparation of an environmental impact statement by the agency. Indeed, the collection of garbage every day from a single block in New York City would seem to have far more potential effect on the environment than essentially any of the types of destruction of articles that these subparagraphs are concerned with.

Subparagraphs (6) and (7) of subsection (b) are concerned with regulations establishing labeling requirements and standards, and we are completely at a loss to understand on what basis such actions could ever have a significant effect on the environment. Subparagraphs (11) and (12) deal with approval of food additive and color additive petitions, and we would submit that it would be extremely rare that, if indeed it would ever happen, that such an approval would have a significant effect on the environment within the meaning of the National Environmental Policy Act.

Subparagraph (e) states that the failure to include an adequate environmental impact analysis report with an application for petition of the type covered in subparagraph (b) Section 6.1 shall be grounds to refuse to accept or file the application for petition. We will confine our remarks to food additive petitions and color additive petitions (including the proposed revisions to Sections 3.4 and 121.51 of the regulations) and would point out that Sections 409 and 706 of the Food, Drug and Cosmetic Act fully set forth the matters that must be dealt with in such petitions and fully set forth the grounds on which such petitions may be denied and there is no provision in those sections for a requirement that the petitions contain an environmental impact analysis report. It is manifest that FDA has no authority to refuse to file such a petition or to deny such a petition because it does not contain such a report.

Subparagraph (g) purports to set forth the contents of the environmental impact analysis report which must be submitted to FDA in connection with any of the types of matters listed in subparagraph (b). As mentioned in our general remarks, we find no authority whatsoever for the imposition of such a requirement.

Section 6.2 - Since this section merely covers the preparation by the agency of environmental impact statements, we have no comment, except to point out that there should be language recognizing the obligation of the agency to maintain as confidential trade secret information which it has received from regulated companies.

Section 6.3 - As before mentioned, we know of no authority in the agency to impose upon industry the obligation to prepare environmental impact analyses reports and we take exception to this section to the extent that it purports to impose requirements for preparation, review, comments, public hearings, etc. with respect to such reports.

To the extent that this section deals with the agency's obligation to prepare environmental impact statements, our only comment is that this section should specifically acknowledge the obligation of the agency to maintain trade secret information in confidence. As to subsection (b) of Section 6.3, our earlier comments with respect to subparagraphs (2) through (5) of Section 6.1(b) apply.

Section 6.6. - Our only comment is that this section should acknowledge the responsibility of the agency to maintain trade secrets in confidence.

In closing, let me emphasize that the Manufacturing Chemists Association and its members are perfectly willing to assist FDA in carrying out its responsibilities under the National Environmental Policy Act. However, the proposed regulations, we submit, are based on a misconception of the scope of the agency's obligations under that statute and, to the extent that they attempt to impose obligations on the affected industries, they are without statutory support.

We appreciate the opportunity to comment on this proposed rule-making.

Sincerely yours,