HFD-30C

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

APR 14 1976

Mr. John D. O'Brien
Seyfarth, Shaw, Fairweather
& Geraldson
1919 H Street, N.W.
Washington, D.C. 20006

Dear Mr. O'Brien:

This is in reply to your letter of April 11, 1975 objecting to the final regulations published in the Federal Register of March 14, 1975 (40 FR 11865) relating to "Asbestos-Form Particles in Drugs for Parenteral Injection."

Specifically, your submission was directed to that portion of the regulations which defined a non-fiber releasing filter as a non-glass fiber filter. You allege that the Commissioner issued the final regulations contrary to the rulemaking provisions of the Administrative Procedure Act in that the final regulations included a substantive provision not set forth in the proposed regulation. Further, you allege that as a result, interested persons were precluded from presenting written data, views and arguments concerning glass fiber filters.

We have carefully considered the arguments that you have presented for withdrawing that portion of the final regulation dealing with glass fiber filters. It is our conclusion that, although the terms of the notice are broad enough to include glass fiber filters, the lack of comments on the proposal with respect to the glass fiber filter issue, indicates that the proposal may not have provided sufficient notice that the phrase "asbestos-containing or fiber-releasing filter" embraces glass fiber filters. Therefore, an amendment to § 211.40(j)(1) will be published in the Federal Register so that the use of glass fiber filters will not be prohibited.

The FDA maintains, however, that there is sufficient scientific data that suggest that the presence of glass fibers in parenteral drugs is of sufficient concern to require Agency action to prohibit the use of glass fiber filters in the manufacture of parenteral drugs for human use. Therefore, we intend, in the very near future, to propose that

75P-0261

Signed ... 4/12 4/12
To Mr. ... C00067/ANS

glass fiber filters be specifically included in the definition of a fiber-releasing filter.

Sincerely yours,

Sam D. Fine
Associate Commissioner
for Compliance

SEYFARTH, SHAW, FAIRWEATHER & GERALDSON
1819 H STREET, N.W.
WASHINGTON, D.C. 20006
AREA CODE 202 872-1300

CHICAGO OFFICE
111 WEST JACKSON BLVD.
CHICAGO, ILLINOIS 60604
AREA CODE 312 431-9000
CABLE ADDRESS: INTERLEX

CALIFORNIA OFFICE
1801 CENTURY PARK EAST
LOS ANGELES, CALIF. 90067
AREA CODE 213 277-7200

April 11, 1975

Miss Jennie Peterson
Hearing Clerk
Food and Drug Administration
Room 6-86
5600 Fishers Lane
Rockville, Maryland 20852

Re: Objections to Order and Regulations Under Caption 'Asbestos Particles in Food and Drugs' (FEDERAL REGISTER, VOL. 40, NO. 51 March 14, 1975).

Dear Miss Peterson:

Johns-Manville Fiber Glass Inc. and Johns-Manville Sales Corporation (hereinafter variously referred to as "Johns-Manville" or "J-M") through its attorneys and pursuant to 21 U.S.C. § 371 of the Federal Food, Drug and Cosmetic Act (hereinafter referred to as the "Food and Drug Act"), 5 U.S.C. § 553(e) of the Administrative Procedure Act (hereinafter referred to as the "APA") and Section 2.67 of the Food and Drug Administration's Rules and Regulations (21 C.F.R. § 2.67) hereby objects to the Commissioner's Order

75P-0261

C67

and Regulations made public on March 14, 1975 in the FEDERAL REGISTER, VOL. 40, NO. 51 page 11865 et seq.

The particular provisions of the aforesaid Order and Regulation to which J-M objects are those pertaining to glass fiber filters used in the manufacture, processing or packaging of components of drug products for parenteral injection in humans. As grounds in support of its objections Johns-Manville states the following:

1. The Order and Regulations have been issued contrary to the rule making provisions of § 371 of the Food and Drug Act as well as the rule making provisions set out in § 553(b) and (c) of the APA. More specifically the Commissioner in the Notice of Proposed Rule Making, entitled, "Asbestos Particles in Food and Drugs" (38 Fed. Reg. 27076) did not make any reference to glass fiber filters and thereby failed to describe all the substances or subjects and issues involved in his proposed notice made public on September 28, 1973. Therefore interested persons were not notified that

the regulation of glass fiber filters was encompassed by the notice.

2. The Commissioner's failure to mention glass fiber filters in the proposal precluded interested persons from an opportunity to participate in the rule making by presenting written data, views and arguments, as required not only by § 371(e)(1) of the Food and Drug Act but also by § 551(b)(3) and (c) of the APA.

3. Johns-Manville manufactures and sells a large number of fiber glass products, including a product line sold under the tradename, "MICRO-FIBER". This product is utilized by J-M's customers in the manufacture, among other things, of glass fiber filters ultimately sold to and utilized by pharmaceutical companies and others in the manufacture, processing or packaging of components of drug products for parenteral injection in humans. The net sales derived by Johns-Manville in the manufacture and sale of glass fiber products sold to outside customers, is approximately $240 million annually of which a substantial amount is derived

from the sale of "MICRO-FIBER".

4. The Commissioner's failure to comply with the statutory rule making provisions cited in paragraph 2, constitutes a denial of administrative due process and deprives the specific provisions objected to herein of having the force and effect of law.

5. The Order and Regulation pertaining to glass fiber filters is arbitrary and unreasonable since it is not based on sufficient data, and has been promulgated without complying with the concepts of fairness and mature consideration, which the rule making provisions of both the Food and Drug Act and the APA were designed to assure.

In support of the foregoing objections Johns-Manville relies on the following facts, arguments and authorities:

FACTS

Notice Of Proposed Rulemaking Relating To "Asbestos Particles In Food and Drugs".

On September 28, 1973, the Commissioner caused to be

published a Notice of Proposed Rulemaking entitled, "Asbestos Particles in Food and Drugs" (38 Fed. Reg. 27076). In this Notice he announced receipt of a petition filed jointly by the Center for Science in the Public Interest and the Environmental Defense Fund. The petition sought promulgation of regulations prohibiting the use of filters containing asbestos in the manufacturing, processing and preparation of food and food additives, as well as drug and drug components on the ground asbestos may be injurious to health when injected or ingested. The petitioners also sought a regulation prohibiting the addition to any drug or drug component of talc containing asbestos particles. In addition, petitioners requested a final regulation requiring a zero tolerance for asbestos particles in talc intended for use as a food additive. This request was pursuant to an earlier proposal published in the FEDERAL REGISTER of August 12, 1972 (37 Fed. Reg. 16407). Finally petitioners requested the Commissioner to take whatever other action he deemed necessary to eliminate contamination of food and drugs by asbestos.

The Commissioner in addressing the petitioners' requests summarized, in some instances, fifty-two (52) cited References to scientific studies relating to the possible relationship between ingestion or parenteral innoculation of asbestos particles and health hazards. These included lung cancer, asbestosis, pleural and peritoneal mesothelioma, gastrointestinal malignancies, and sarcomas. On the basis of these studies he proposed, inter alia, to amend good manufacturing practice (GMP) regulations as follows:

> . . . to require that filtration procedures for parenteral drugs shall utilize either a non-asbestos-containing or non-fiber-releasing filter such as a membrane filter or, if an asbestos-containing filter is necessary, shall also utilize an additional non-asbestos-containing filter or non-fiber-releasing filter such as a membrane filter to reduce asbestos fiber content to the minimum level feasible unless such a subsequent filter will compromise the safety, identity, strength, quality or purity of the product." (38 Fed. Reg. 27079).

However, with respect to the petitioners' request for a final regulation pertaining to zero tolerance for asbestos

particles in talc intended as a food additive, the Commissioner concluded that "a final regulation for talc" could not be "promulgated until a reproducible and accurate method can be specified for compliance purposes." (38 Fed. Reg. 27079). However with respect to food or food packaging material containing talc the Commissioner proposed a new regulation (§ 121.2006) setting out specifications or analytical limitations on the presence of asbestos fibers. He further proposed that any talc used in the manufacture or processing of any drug or drug ingredient would be required to meet these specifications or analytical limitations (38 Fed. Reg. 27079).

Following these proposals in the preamble the Commissioner invited interested persons to comment ". . . on all aspects of the public health significance of ingestion and injection of asbestos fibers." (Emphasis added). (38 Fed. Reg. 27079). December 27, 1973 was established as the final date for receipt of comments.

Commissioner's Order and Final Regulation Relating To "Asbestos-Form Particles In Drugs For Parenteral Injection".

In an Order made public in the FEDERAL REGISTER of March 14, 1975 (40 Fed. Reg. 11865) the Commissioner promulgated the final regulation, certain provisions of which are objected to herein. In the preamble the Commissioner called attention to his September 28, 1973 Notice of Proposed Rulemaking and stated that in it he had proposed, "to restrict the utilization of asbestos filters in the manufacturing of parenteral drugs and parenteral drug ingredients" (40 Fed. Reg. 11865). Thereafter he set out his reactions and responses to the comments which had been received pursuant to that Notice. Further, he stated that these comments fell into two (2) categories. Those in the first category concerned "provisions to decrease the potential for ingestion of asbestos fibers" and those in the second category concerned, "provisions to decrease the potential for injection of asbestos fibers".

In Part A of the preamble the Commissioner set out his reactions and responses to comments in the first category.

He withdrew the proposed analytical limitations on the presence of asbestos fibers in talc used in the manufacture of food, food packaging material and drugs or drug ingredients. In this regard he said:

> The Commissioner therefore concludes that the comment has demonstrated that the asbestos content of talc used in the manufacture of food- or drug-contact paper and paperboard does not represent a potential contaminant of packaged food or drugs, as assessed by currently available methodolgy. (40 Fed. Reg. 11866).

With respect to petitioners' request to prohibit asbestos filters in the preparation of food and beverages and non-parenteral drugs, the Commissioner decided to delay promulgation of a final regulation. He also declined to issue a final regulation as to the amount of asbestos fibers in talc for use in food and drugs or which might migrate into food or drugs from talc-containing packaging materials. He stated, in effect, his analysis of comments received on the potential for ingestion of asbestos fibers from these sources rendered

their regulation, "unwarranted until more reliable data . . . [could] be obtained concerning these matters." (40 Fed. Reg. 11867).

In Part B of his preamble to the 1975 Order and Regulation, the Commissioner described his 1973 proposal as follows:

> In order to deal with the injection potential of asbestos fibers, the Commissioner proposed that the good manufacturing practice regulations for drugs be amended to require that filtration procedures for parenteral drugs shall utilize either a non-fiber-releasing filter such as a membrane filter or, if an asbestos-containing filter is used because it is necessary, the procedures shall also utilize an additional non-asbestos-containing or non-fiber-releasing filter such as a membrane filter to reduce asbestos fiber content to the minimum level feasible unless such a subsequent filter will compromise the safety, identity, strength, quality, or purity of the product. (40 Fed. Reg. 11867).

The Commissioner then addressed himself to comments in the second category, namely, those dealing with the injection potential of asbestos fibers in parenteral drugs. A number

of comments, according to the Commissioner, claimed there is no conclusive evidence that asbestos filters add fibers to filtrate, or that asbestos has caused deleterious effects as a result of parenterally administered drugs. The Commissioner disagreed, indicating that investigation by the Food and Drug Administration had revealed direct evidence that utilization of asbestos filters can cause asbestos contamination. Then citing References 1, 11, 12 and 13, the Commissioner announced it was necessary to minimize asbestos contamination in parenteral products. More specifically he stated:

> . . . the Commissioner has determined that it is important that asbestos-containing filters be replaced with non-fiber-releasing filters unless it is demonstrated that it is not possible to manufacture a safe and effective parenteral drug or parenteral drug ingredient without the use of such an asbestos-containing filter.

Another comment under the second category expressed concern that replacement of asbestos-containing filters would upset delicate filtration parameters in the product processes.

Hence an eighteen (18) month period to meet the replacement requirement was suggested, in order to allow time for technical development of new processes. The Commissioner agreed and granted eighteen (18) months to achieve compliance and established a requirement for monthly progress reports in the case of firms unable to achieve compliance within twelve (12) months after the effective date of the Regulation (40 Fed. Reg. 11868).

A significant number of comments noted by the Commissioner expressed concern that discontinuance of asbestos-containing filters would cause many parenteral products to suffer in safety or quality. To these comments the Commissioner's reply was that the burden would be on parenteral drug manufacturers to make such a showing.

One comment objected to the utilization of the terms "membrane filter" and "non-fiber-releasing filter". The Commissioner agreed that the regulation should not specify only one type of substitute filter which would satisfy the new requirement. He thus deleted the term "membrane filter"

from the final regulation. However he refused to delete the term "non-fiber-releasing filter", stating:

> The Commissioner also concludes that for the purposes of these regulations, a non-fiber-releasing filter shall be defined as a non-asbestos, nonglass fiber filter which after any appropriate pretreatment such as washing or flushing, will not continue to release fibers into the drug or drug ingredient which is to be filtered. (Emphasis added). (40 Fed. Reg. 11867).

As justification for extending, for the first time, the September 28, 1973 proposal to include glass fiber filters, the Commissioner relied on two references, both of which were published in 1974, after the time had expired for receipt of comments on the original proposal. With respect to these references the Commissioner stated:

> As the similarity between the carcinogenicities of asbestos and fibrous glass has been noted, fibrous glass filters have been added to this definition to prevent the widespread conversion

from asbestos to this type of filter. (Emphasis added). (Ref. 14 and 15)*

ARGUMENT

Substantive Regulations And Their Amendments Promulgated By Federal Agencies Without Full Compliance With Statutory Rule Making Provisions Are Invalid.

At the outset it is to be noted that the rule making provisions of not only the Food and Drug Act but also those of the APA apply to the Commissioner's action herein. It has been held that § 701 et seq. of Title 5, of the APA, relating to the scope of judicial review, and § 371 of the Food and Drug Act must be construed together. Osyter v. Ewing, (CA 9 1949) 74 F.2d 676, cert. denied 70 S.Ct. 101,

---

* Ref. 14. "Symposium on Occupational Exposure to Fibrous Glass," sponsored by National Institute for Occupational Safety and Health, University of Maryland, June 26, 27, 1974.

Ref. 15. Stanton Mearl F., "Fiber Carcinogenesis: Is Asbestos the Only Hazard?" "Journal of the National Cancer Institute," 52:633 (1974).

338 U.S. 860, Rehearing denied 70 S.Ct. 793, 339 U.S. 945. Here the Commissioner's Order and Final Regulation was issued under § 351 of the Food and Drug Act as well as its § 371 dealing with rule making. Paragraph (e)(1) of this latter section states in relevant part:

> Any action for the issuance, amendment, or repeal of any regulation under section . . . 351(b) . . . of this Title shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. (Emphasis added).

This provision comports with the rule making provisions of § 553 of the APA. Section 553 of that section mandates adequate notice and an opportunity for participation in rule making by interested persons. With respect to the adequacy of notice, § 553(b) provides:

> General notice of proposed rule making shall be published in the Federal Regis-

> ter, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include -
>
> (1) a statement of the time, place, and nature of public rule making proceedings;
>
> (2) reference to the legal authority under which the rule is proposed; and
>
> (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Following the foregoing is the provision granting interested persons a statutory right to participate in rule making:

> After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. (§553(c)).

With the exceptions of interpretive rules; general statements of policy; rules of agency organization, procedure or practice; or where good cause exists making public procedure, impracticable, unnecessary or contrary to the public interest (5 U.S.C. § 553(b)(A) and (B)); agencies are required to comply with the foregoing notice provisions. Where

no notice is given prior to final promulgation of a substantive regulation (or amendment) such regulation is invalid. Texaco Inc. v. Federal Power Commission, 412 F.2d 740 (CA 3 1969) and Pharmaceutical Manufacturer's Association v. Finch, 307 F.Supp. 858 (D.C.Del. 1970).

Referring to the notice and public participation provisions in § 553 of the APA the Third Circuit in Texaco stated:

> These procedures must be followed when an agency is exercising its legislative function in order that its rules have the force of law. Cf. N.L.R.B. v. Wyman-Gordon Company, 394 U.S. 759, 89 S.Ct. 1426, 22 L.Ed. 2d 709. (Id. 412 F.2d at 744).

There the Federal Power Commission established a regulation requiring that a monthly compound interest rate would be added to amounts ordered refunded pursuant to the Natural Gas Act. No notice of this proposal was made. On a petition filed by a natural gas company to review and set aside this regulation, it was contended, ". . . that this new rule was promulgated without giving . . . any notice

[to natural gas companies] of [an] opportunity to participate in the rule making through the submission of written data, views, or arguments thus violating . . . the Administrative Procedure Act, 5 U.S.C. §553(b) and (c)." (Id. p. 742). The F.P.C. asserted that there existed good cause for dispensing with public notice as "unnecessary" because of the minor nature of the regulation. The Third Circuit disagreed. It concluded that the regulation was substantive and therefore did not come within the exceptions to notice embodied in § 553 (b)(A) or (B). Consequently it held the regulation to be invalid. In concluding that interest compounded monthly on refunds was a substantial matter, the Court noted the regulation "would effect numerous jurisdictional natural gas companies and potentially involve large sums of money."

Here the Commissioner by stating that glass fiber filters were added to the final regulation, has admitted non compliance with statutory notice provisions. Thus the Commissioner, as did the Federal Power Commission in Texaco, has announced a general rule, substantial in nature, and which will have an adverse effect on Johns-Manville as well as others. In

addition by failing to give notice of a proposal to regulate glass fiber filters, the Commissioner has thwarted the purpose of the mandatory notice requirements. The purpose of those requirements was described by the Third Circuit in Texaco as follows:

> Section 553 was enacted to give the public an opportunity to participate in the rule-making process. It also enables the agency promulgating the rules to educate itself before establishing rules and procedures which have a substantial impact on those regulated. [Citation omitted]

In a similar case and one involving this Agency, Pharmaceutical Manufacturer's Association v. Finch, supra, it was held that a rule promulgated by the Commissioner was "substantive", rather than "interpretive", and therefore was not removed from the notice requirement of § 553. Since there had been a failure to comply with that requirement, the regulation was held to be invalid.

In the Finch case it was argued that notice preceding a regulation setting new standards of evidence showing the

efficacy of drug products, was unnecessary, since the regulation was merely procedural and interpretive of a statutory provision. Therefore the Commissioner claimed it fell within an exception to the statutory rule making provisions of the APA. Like a similar argument in Texaco, this argument was rejected. The court citing Columbia Broadcasting Systems, Inc. v. United States, 316 U.S. 407, 416, ruled that the notice provision of § 553 cannot be avoided simply by designating a regulation as "interpretive" rather than "substantive". It held it was not bound by the label placed on it by the Commissioner but rather was entitled to make its own determination as to whether or not the regulation was substantive. After disposing of these preliminaries the court held that the regulation in question was substantive since it would have a "substantial impact" on the drug industry. It further held that non compliance with the notice provisions of § 553 of the APA rendered the regulation invalid.

In the instant case there can be no question but that the final regulation relating to the use of glass fiber filters in the manufacture etc. of parenteral drugs is

substantive. Insofar as the Commissioner has stated in the preamble that he finds the carcinogenicities of asbestos and fibrous glass to be similar, the adverse effect of the regulation on J-M and the entire multi-billion dollar glass fiber industry could be far reaching indeed. The banning or restricting of glass fiber filters in the manufacture etc., of parenteral drugs, based on the Commissioner's finding of a potential health hazard associated with fibrous glass, raises a very substantial cloud of suspicion over the safety of the manufacture, sale and use of all glass fiber products produced and sold by J-M, as well as by other glass fiber manufacturers. At a very minimum, it will carry an implication of suspicion over all applications of glass fiber filters in the manufacture etc., of foods, beverages, and non-parenteral drugs. Immediately, the regulations will not only adversely affect J-M, but it will also have a substantial impact on glass fiber filter manufacturers, pharmaceutical companies producing parenteral drugs and companies engaged in the packaging of such drugs.

Moreover the Commissioner apparently concedes the sub-

stantive nature of the regulation since in promulgating it he cited § 371, the rule making provision of the Food and Drug Act. Thus in the instant case unlike Finch and Texaco, there is no question whether the regulation falls within an exception to the notice requirements of the APA. Therefore it is clear that the inquiry in the instant case should be addressed to whether the Commissioner has given any notice, rather than whether the 1973 notice was proper or adequate.

The Preamble To The Final Order And Regulation Clearly Shows A Failure To Give Any Notice To Regulate Glass Fiber Filters; Therefore This Aspect Of The Final Regulation Is Invalid.

A review of the documents leading to and incorporating the final regulation shows this case is actually one in which no notice, rather than improper or inadequate notice was given. In the 1973 Notice of Rulemaking the Commissioner did not mention or allude to either glass fibers or glass fiber filters. Moreover in his preamble to the 1975 Order and Regulation the Commissioner admitted that glass fiber filters were added to the final regulation. In this regard he said:

> As the similarity between the carcinogenicities of asbestos and fibrous glass have been noted, fibrous glass filters have been added to . . . [the definition of a non-fiber-releasing filter] to prevent the widespread conversion from asbestos to this type of filter (Ref. 14 and 15).

The legal effect of the Commissioner's above noted admission, is to render the regulation invalid since there was no notice at all of a proposal to regulate glass fiber filters. It is thus submitted this case is in point with Texaco and Finch. In those cases there was no notice of rule making preceding issuance of final regulations of general application. Attempts to justify lack of notice were made in both, based on claims that the final regulations fell either within the interpretive or "unnecessary" exceptions to the notice requirements of § 553. In both cases the courts rejected these defenses holding that the regulations, having general application, were substantive because of their widespread effect on those regulated. The same is true here. In reaching their decisions both courts looked to the policy underlying the requirement for notice in rule making, and cited the Supreme Court's plurality

opinion in N.L.R.B. v. Wyman-Gordon Company, 394 U.S. 759 89 S.Ct. 1426. There it was stated that the rule making provisions of the APA "were designed to assure fairness and mature considerations of rules of general application."

On the basis of these authorities and the Commissioner's admission in the preamble of his final order and regulation that glass fiber filters were "added" to the regulation proposed in 1973, it is clear that no notice whatsoever has been given either in accordance of § 553 of the APA or § 371 of the Food and Drug Act. Consequently the Commissioner in promulgating his final regulation has failed to comply with the letter and spirit of the statutory notice provisions. He has thwarted the Congressional policy upon which they are founded. As the Third Circuit noted in Texaco, one of the purposes encompassed by the policy upon which the rule making provisions are based is to allow agencies:

> to educate . . . [themselves] before establishing rule and procedures which have a substantial impact on those regulated. (Id. at 744).

See also, Pharmaceutical Manufacturers Association v. Finch, supra, and National Motor Traffic Association v. U.S., 268 F.Supp. 90, 95-97 (D.C.C. 1967) aff'd., 393 U.S., 89 S.Ct. 49 (1968).

We are cognizant of precedent to the effect that regulatory agencies in formulating final regulations, are entitled to exercise their own expertise and in so doing, have discretion to look beyond comments or views received during the informal rule making process. However this discretion is not unlimited.* Here the Commissioner abused his discretion by relying on a scientific study and proceedings of a symposium, neither of which were published during the period of time for receipt of comments. In the Finch case, the court strongly

---

* In passing we would note that by making this contention we do not address ourselves to the merits of this regulation, nor did the courts in Texaco or Finch. In Texaco, the court in striking down the FPC's regulation noted at page 745:

> We need not and do not express any opinion on the merits of the challenged rule.

suggested that the Congressional policy of affording agencies an opportunity to fully educate themselves during the rule making process, requires an opportunity for comment on scientific data available during the comment period and before promulgation of a final rule. Here, the Commissioner relied on scientific data which had not been published prior to the expiration of the comment period without affording an opportunity for comment on that data or its subject matter, fibrous glass. Therefore, he abused his discretion and thwarted Congressional policy underlying the rule making process. This, and his admission that he added "fibrous glass" to the purview of the final regulation, are in and of themselves sufficient to show non compliance with statutory rule making provisions and to warrant an immediate withdrawal of the final regulation, as it pertains to glass fiber filters.

Even Assuming This Case Is Viewed As Involving A Question Of Proper Notice, Rather Than A Question Of No Notice, The Conclusion Is Warranted That The Notice Was Improper.

A review of the 1973 Notice of Proposed Rulemaking, as

well as the preamble and final order, discloses that the scope of the notice of proposed rule making with respect to the manufacture etc. of parenteral drugs, was limited solely to asbestos filters. Support for this is shown by the following:

First, the notice of rule making was captioned, "Asbestos Particles in Food and Drugs" (38 Fed. Reg. 27076).

Second, in the notice, preamble and proposal the word "asbestos" appears sixty-two (62) times, the phrase "asbestos fibers" appears forty-one (41) times, and in the proposed regulation the phrase "asbestos filters" appears eight (8) times.

Third, in his conclusions in the preamble to the notice relating to filtration procedures for parenteral drugs, the Commissioner stated he had concluded to take action either to "require that filtration procedures for parenteral drugs shall utilize . . . a non-asbestos-containing . . . filter", or to allow the use of such a filter only where necessary not to "compromise the safety, identity, strength, quality

or purity of the product."

Fourth, in his first conclusion to the preamble of the notice, the Commissioner stated that the purpose of his proposal was ". . . to reduce asbestos fiber content to the minimum level feasible." (Emphasis added). (38 Fed. Reg. 27079).

A fifth basis for supporting the contention that the scope of the proposal was limited to a concern to eliminate or reduce asbestos fibers in parenterally administered drugs, is found in that portion of the 1973 Notice, wherein the Commissioner requested comment on his proposals. The comments requested by him were limited to ". . . public health significance of ingestion and injection of asbestos fibers." (Emphasis added). (38 Fed. Reg. 27079).

A sixth basis in support of the contention that the scope of the notice was limited to a proposal to bar or reduce asbestos fibers in parenteral drug filtration processes, is shown in the Commissioner's characterization of his 1973 proposal in the preamble to his 1975 Order and

Final Regulation. In the first paragraph of the preamble he stated that in 1973 he had proposed, ". . . to restrict the utilization of asbestos fibers in the manufacture of parenteral drugs and parenteral drug ingredients." (40 Fed. Reg. 11865). The Commissioner then describes the comments received pursuant to his 1973 Notice and states they fall into two categories. Those in the first category, he said, concern "provisions to decrease the potential for ingestion of asbestos fibers." (Emphasis added). Those comments received in the second category concern "provisions to decrease the potential for injection of asbestos filters." (Emphasis added).

Finally, the very nature of the comments received pursuant to the notice, were generally limited either to the issue of ingestion or injection of asbestos fibers. Hence these comments support our contention that the scope of the notice as understood by those responding, was limited to a proposal to regulate the adulteration of food and drugs by asbestos fibers and particles.

When one considers the plethora of evidence showing that the scope of the notice was limited to a proposal to regulate asbestos fibers and particles, the notice is not made adequate or proper with respect to glass fiber filters, simply because the terms "release fibers" and "fiber releasing filter" were used in the proposed regulation (§ 133.8(j), 38 Fed. Reg. 27080). Based on all of the evidence cited avove, one can reach no other conclusion but that the Commissioner's use of the word "fiber" within these terms referred solely to "asbestos fibers" and he was using these two (2) words ("asbestos" and "fibers") synonomously. As the plurality opinion noted in N.L.R.B. v. Wyman-Gordon, supra, compliance with "the substance" of the rule making requirements of the APA requires a notice published in the FEDERAL REGISTER stating "the terms or substance" of the proposed rule. Greater specificity than merely the use of these general terms would have been necessary for compliance with this requirement. Therefore, it cannot successfully be argued that the Commissioner's notice was broad enough to put interested persons on notice that his proposal related

to the entire range of fiber releasing filters used in the manufacture etc. of parenteral drugs.

Support for our contention as to the inadequacy of the notice is found in Wagner Electric Corporation v. Volpe, 46 F.2d 1013 (CA 3 1972). There the National Highway Safety Traffic Administration published a notice of proposed rule making to amend a regulation incorporating an SAE (Society of Automotive Engineers) standard. This standard governed performance criteria for vehicle hazard warning signal flashers and provided sampling and testing provisions designed to assure compliance with that criteria. In his notice of rule making the Administrator simply proposed "omitting sampling provisions" of the SAE standard. However, in the final regulation issued without further notice, not only were sampling provisions eliminated but performance criteria of the standard were substantially downgraded. The effect of the regulation was to reduce the permissible failure rate to a relatively insignificant level. The Administrator argued the notice had included sufficient description of the subjects and issues involved so as to

put interested persons on notice that the proposal related to the entire standard on vehicle hazard warning flashers. He therefore claimed the notice had complied with § 553(b) of the APA. The Third Circuit disagreed. It held that the notice related only to the omission of sampling provisions and therefore was insufficient to put interested persons on notice that a proposal relating to the entire standard was being made. Consequently the court set aside the order announcing the final regulation and at page 1020 of its opinion said ". . . we conclude that there was no adequate notice of proposed rule making."

Wagner holds that an agency may not in a notice of proposed rule making, indicate an intention to regulate subject or substance A and thereafter include subject or substance B as well as A in a final regulation. It supports our contention that there must be greater specificity as to the subject or substance to be regulated than was given in the Commissioner's 1973 Notice. Wagner is analogous to the present case, in that the Administrator expanded the final regulation to include performance criteria, whereas here the

Commissioner expanded the final regulation to include glass fiber filters. Since agency action in both cases is essentially the same, the Wagner Electric decision supports a conclusion that the notice herein did not comply with the requirements of the APA.

The foregoing conclusion is warranted even though two comments were received which suggested, "all extraneous material such as diatomaceous earth carbon, silica, microfiberglass, etc.," should also be regulated (40 Fed. Reg. 11867). In the Wagner Electric case the Administrator in arguing the notice was sufficient to apprise interested persons that an amendment to the entire hazard warning flasher standard had been proposed, pointed to comments received from certain manufacturers. He relied on the fact that in these comments received in response to the notice, some manufacturers had discussed the desirability of downgrading performance criteria, if permissible failure rates were eliminated. The court rejected the Administrator's argument as to adequacy of the notice stating:

> The fact that some knowledgeable manufacturers appreciated the intimate relationship between the permissible failure rate provisions and the performance criteria, and so responded, is not relevant. Others possibly not so knowledgeable also were interested persons within the meaning of 5 U.S.C. § 553. (Id. p. 1019).

The Wagner Electric ruling in this regard is equally applicable to the instant case. Thus two (2) comments received by the Commissioner which suggested extension of the proposed regulation to "micro-fiberglass', cannot support a conclusion that the notice was adequate enough to comply with the APA.

It is our contention that when the Commissioner received these two (2) comments and became aware of the publication of References 14 and 15, he should have proposed a new notice of proposed rule making, expanding the September, 1973 proposal to include glass fiber filters -- assuming the Commissioner believed that these two comments and References tended to support the need to propose a regulation of glass fiber filters. As a matter of fact, this is exactly what the Commissioner did with respect to talc containing asbestos.

The Commissioner's August, 1972 Notice proposed to regulate the uses of talc-containing asbestos in food and food packaging. In his September, 1973 Notice the Commissioner expanded this proposal to also include drugs and drug packaging. At such time as the Commissioner decided that there were grounds upon which to propose to regulate certain uses for glass fiber filters, he should have, and was required to, publish a new notice of proposed rule making, expanding the September 1973 proposal to include glass fiber filters, and citing the evidence supporting such a proposal.

CONCLUSION

We request that the regulation, insofar as it pertains to glass fiber filters in the manufacture etc. of parenteral drugs immediately be withdrawn and that a hearing on the issues raised by these objections be ordered by the Commissioner under § 701 of the Food and Drug Act. It is submitted that the facts, arguments and precedents presented above establish reasonable grounds for these objections, which warrant a hearing on the issues they pose. These requests are reasonable,

not only because of the immediate adverse effect of the regulation on the "MICRO-FIBER" segment of Johns-Manville's business, but also because the regulation places a cloud of suspicion, from a health standpoint, over all of J-M's glass fiber products as well as the glass fiber products manufactured and sold by all other companies. Finally, it is represented that these objections are not being interposed to delay or impede effective enforcement of the Act.

Respectfully submitted,

JOHNS-MANVILLE FIBER GLASS INC. and
JOHNS-MANVILLE SALES CORPORATION

By John D. O'Brien
John D. O'Brien

Their Attorney

SEYFARTH, SHAW, FAIRWEATHER
& GERALDSON
1819 H Street, N. W.
Suite 750
Washington, D. C. 20006
(202)872-1300

Dr. Schonwalder HFS-30
Ms. McEvoy HFD-30
Ms. Wylie HFF-30
4/15/75