



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857
November 25, 1980

John F. Banzhaf, III
Peter N. Georgiades
Action on Smoking and Health
2000 H St., NW
Washington, DC 20006

Re: Docket Nos. 77P-0185
78P-0338/CP

Dear Messrs. Banzhaf and Georgiades:

This replies to the pending requests in the petitions filed by Action on Smoking and Health (ASH), et al., on May 26, 1977 (Petition No. 1) and on October 2, 1978 (Petition No. 2), and supplements to them. Your petitions request the Food and Drug Administration (FDA) to recognize its jurisdiction over the following as medical devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h):

- (1) Cigarettes containing nicotine (Petition No. 1);
- (2) Cigarette filters, which you describe as basically "the 'detached' filter, which is purchased separately from the cigarettes and is installed by the smoker on the end of the cigarette" and "the 'attached' filter [which] ... is an integral part of many brands of cigarette" (Petition No. 2, pp. 5-6).

ASH also requests that FDA commence rulemaking to determine an appropriate scheme for regulating cigarettes and cigarette filters as medical devices.

We will respond first to Petition No. 1 concerning cigarettes containing nicotine and next to Petition No. 2 concerning cigarette filters. Because we agree with your statement (Petition No. 2, p. 6) that "it is conceptually easier to discuss detached and attached filters separately," we will respond separately with respect to "attached" and "detached" filters. Finally, we will respond to your request that FDA commence rulemaking to determine an appropriate

regulatory scheme. In preparing our response, we have considered the comments and other documents filed with the respective petitions in the Dockets Management Branch (formerly the Hearing Clerk's office) as well as the petitions themselves.

I. Cigarettes Containing Nicotine

For the reasons discussed below, we are denying the pending requests in Petition No. 1 concerning cigarettes containing nicotine as "devices."

Petition No. 1 (p. 31) sets forth your view that "cigarettes containing nicotine could be regulated either as 'drugs' or as 'devices.'" As you know, on December 5, 1977, we denied your request to recognize jurisdiction over cigarettes containing nicotine under the definition of "drug" in section 201(g) of the Act, 21 U.S.C. 321(g). That denial has been extensively briefed, both before the District Court and the United States Court of Appeals for the District of Columbia, where the matter is presently pending. (ASH v. Harris, D.C. Cir., No. 79-1397). The "drug" issue will not be further discussed here.

Petition No. 1 broadly requests (e.g., p. 31) that FDA recognize jurisdiction over cigarettes as a "device" under section 201(h) of the Act, but does not specifically assert or present evidence that cigarettes are a "device" under the provisions of clauses (1) or (2) of section 201(h), 21 U.S.C. 321(h)(1) or (2). We find that cigarettes are not recognized in the official National Formulary or the United States Pharmacopeia, or any supplement to them, and that there is no evidence in the petition that cigarettes are intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals. Accordingly, insofar as Petition No. 1 may be deemed to request that FDA regulate cigarettes containing nicotine as a "device" under section 201(h)(1) or (2) of the Act, we deny your request.

With respect to the application of section 201(h)(3) of the Act, 21 U.S.C. 321(h)(3), Petition No. 1 asserts that when the definition of "device" was enacted in 1938 it was intended to expand the agency's jurisdiction beyond that provided over "drugs" (p. 30) and that the "device" category is a far broader category than that of "drug" (p. 31).

The legislative history of the development of the definitions of "drug" and "device" as enacted in 1938 is discussed at length by the Supreme Court in United States v. An Article of Drug ... Bacto-Unidisk, 394 U.S. 764, 794-800 (1969), where the Court treats the interpretation of the "intended use" portion of both definitions as presenting the same issues when considered under either section 201(g) or then 201(h). The language of current section 201(h)(3) was contained in the "device" definition prior to the "Medical Device Amendments of 1976," (the amendments), Pub. L. 94-295. Petition No. 1 fails to establish that there are any differences between the scope of "device" jurisdiction before and after the amendments that are pertinent to determining whether cigarettes containing nicotine are "intended to affect the structure or any function of the body of man" within the meaning of section 201(h)(3) of the Act. Also, there is no suggestion in the legislative history of the amendments that Congress intended that portion of the definition to be interpreted in a different manner than it had been previously or than the identical language found in the "drug" definition in section 201(g)(1)(C) of the Act, 21 U.S.C. 321(g)(1)(C).

The report on the amendments by the House Committee on Interstate and Foreign Commerce (H.R. Rep. No. 94-853, 94th Cong., 2d Sess., p. 14 (1976)) notes that the purpose of amending the definition is "to draw a clear distinction between a 'device' and a 'drug';" that the definition generally retains provisions of existing law concerning intended use; that those characteristics are also used in the definition of a "drug" in section 201(g) of the Act; but, adds the chemical action and metabolism modification to "remov[e] the gray area that exists under present definitions."

Specifically, there is no evidence in the legislative history that Congress intended to include cigarettes within the definition of "device" nor does the legislative history contain any discussion of a possibility that cigarettes were "devices" within the prior definition.

The amendments were thoroughly considered, and the legislative history discusses the types of products intended to be regulated and the types of health hazards with respect to which the amendments were intended to provide authority. Cigarettes are not mentioned even though Congress was aware of the considerable public discussion of the health hazards of cigarette smoking. It is, therefore, not reasonable to consider cigarettes as "devices" when there was no discussion in the legislative history of congressional intent to provide jurisdiction over cigarettes or to provide authority suitable to the regulation of cigarettes.

FDA has long believed and has repeatedly advised inquirers that cigarettes as customarily marketed are intended solely for smoking purposes or smoking pleasure and are not within FDA's jurisdiction under the Act. Indeed, this interpretation is involved in the pending appeal in ASH v. Harris. FDA's long-standing interpretation that it has no jurisdiction over cigarettes, absent evidence of the requisite intended use which brings cigarettes within the Act, is well known. That "statutory construction has been 'fully brought to the attention of the public and the Congress,' and the latter has not sought to alter that interpretation although it has amended the statute in other respects, [thus,] presumably the legislative intent has been correctly discerned." United States v. Rutherford, 99 S.Ct. 2470, 2476 n.10 (1979).

As stated, Congress has long been aware of the agency's interpretation. See, e.g., Hearings Before the Committee on Interstate and Foreign Commerce, House of Representatives, 89th Cong., 2d Sess., on Bills Regulating the Labeling and Advertising of Cigarettes and Relating to Health Problems Associated with Smoking, pp. 13-19 (1964); Hearings Before the Committee on Interstate and Foreign Commerce, House of Representatives, 89th Cong., 1st Sess., on H.R. 2248, etc., Cigarette Labeling and Advertising--1965 (1965); Hearings Before the Consumer Subcommittee of the Committee on Commerce, United States Senate, 92d Cong., 2d Sess., on S. 1454, Public Health Cigarette Amendments of 1971, 239-252 (1972). Although bills have been introduced to amend the Act to include cigarettes, these attempts have failed. See, e.g., H.R. 11280, 84th Cong., 2d Sess. (1956) (to establish standards of purity, quality and fitness for human consumption); S. 2554, 85th Cong., 1st Sess. (1957) (label warning requirement); H.R. 592, 85th Cong., 1st Sess. (1957); S. 1682, 88th Cong., 1st Sess. (1963); H.R. 5973, 88th Cong., 1st Sess. (1963); H.R. 2248, 89th Cong., 1st Sess. (1965); H.R. 279, 96th Cong., 1st Sess. (1979). Evidence in the legislative history of those bills indicates that the bills were intended to expand, and not merely to clarify, FDA's jurisdiction under the Act. For example, when Senator Moss introduced S. 1682, he explained that "this amendment simply places smoking products under FDA jurisdiction along with foods, drugs, and cosmetics." 109 Cong. Rec. 10322 (1963).

FDA has, however, occasionally had evidence that cigarettes have been represented as effective for the prevention or treatment of respiratory and other diseases or for weight reduction. FDA has regarded cigarettes which were

so represented by manufacturers or vendors as "drugs". See, e.g., United States v. 46 Cartons... Fairfax Cigarettes, 113 F. Supp. 336 (D.N.J. 1953); United States v. 354 Bulk Cartons ... Trim Reducing-Aid Cigarettes, 178 F. Supp. 847 (D.N.J. 1959).

An article may be within FDA's jurisdiction if there is objective evidence that the manufacturer or vendor intends that the article is to affect the structure or a function of the body. In determining the intended use of a product, FDA considers the expressions of the person legally responsible for its labeling and the circumstances surrounding its distribution. Petition No. 1 does not contain examples of any representations by the manufacturers or vendors of cigarettes establishing that cigarettes are intended to affect the structure or any function of the body of man.

Petition No. 1 (p. 5) asserts that cigarettes per se affect the structure and functions of the body. However, effects alone do not establish jurisdiction under section 201(h)(3) of the Act. Even assuming the accuracy of the assertions as to the effects of cigarettes, the petition does not establish that these effects are intended.

Evidence of consumer intent in using a product can be relevant in determining the intended use of the product, and we have considered the evidence of consumer intent presented in Petition No. 1. ASH asserts that consumers use cigarettes with the intent of affecting the structure or functions of their bodies but the petition does not establish this contention. Indeed, petitioners admit (e.g., Petition No. 1, p. 2) that consumers smoke for a variety of reasons.

After a review of all the evidence on Petition No. 1, we conclude that the evidence presented by petitioners fails to establish that cigarettes are intended "to affect the structure or any function of the body" within the meaning of section 201(h)(3) of the Act.

In addition, we have considered whether granting your request to assert jurisdiction over cigarettes as "devices" would require action precluded by another act of Congress, specifically the Federal Cigarette Labeling and Advertising Act (FCLAA), 15 U.S.C. 1331-1340, as amended (Petition No. 1, pp. 20-30 and Exhibit IX).

In enacting the FCLAA, Congress was aware that FDA does not consider cigarettes, absent evidence of the requisite intended use, to be within FDA's jurisdiction under the Act.

See, e.g., Hearings on H.R. 2248, etc., at 193 (1965). In a March 22, 1965, letter to the Chairman of the Senate Committee on Commerce concerning cigarette labeling and advertising, the Secretary of then Department of Health, Education, and Welfare (HEW) Anthony J. Celebrezze recommended that regulatory authority concerning cigarette labeling be vested in HEW. Secretary Celebrezze argued that HEW should be authorized to require statements on the labeling of cigarette packages and to prohibit or regulate the use of statements that might give consumers the misleading impression that a given cigarette is safer than others. Hearings Before the Committee on Commerce, United States Senate, 89th Cong., 1st Sess., on S. 559 and S. 547, Bills to Regulate Labeling of Cigarettes and For Other Purposes, pp. 22-26 (1965). Secretary Celebrezze recommended that the preferable manner for vesting regulatory responsibility would be by way of amendment to the Federal Hazardous Substances Act (FHSA). Rather than providing the regulatory authority recommended by HEW, Congress mandated a specific warning, and preempted the imposition of a requirement of any other statement relating to smoking and health on cigarette packages. Similarly, Congress opted for the requirement of reports to Congress concerning smoking and cigarette labeling, including recommendations for legislation. We believe that the FCLAA, as amended, and its legislative history is strong evidence that Congress did not intend cigarettes as customarily marketed, and absent evidence of the requisite intended use, to be regulated by FDA under the Act.

We are also mindful of the fact that Congress has specifically excluded tobacco or tobacco products from the coverage of other statutes that otherwise might have applied to them. Thus, tobacco or tobacco products were excluded from the definition of "hazardous substance" under the FHSA, 15 U.S.C. 1261(f)(2); from the definition of "consumer product" under the Consumer Product Safety Act, 15 U.S.C. 2052(a)(1)(B); from the definition of "chemical substance" under the Toxic Substances Control Act, 15 U.S.C. 2602(2)(B)(iii); from the definition of "controlled substance" under the Controlled Substances Act, 21 U.S.C. 802(6); and from the definition of "consumer commodity" under the Fair Packaging and Labeling Act, 15 U.S.C. 1459(a)(1).

Those actions are indicative of the policy of Congress to limit the regulatory authority over cigarettes by Federal agencies. This is particularly true of the amendment of the FHSA to specifically exclude tobacco and tobacco

products from the definition of "hazardous substance," 15 U.S.C. 1261(f)(2), enacted in response to American Public Health Ass'n v. Consumer Product Safety Comm'n, Civil Action No. 94-1222 (D.D.C. April 23, 1975) (Exhibit IX to Petition No. 1). That case had held that the Consumer Product Safety Commission (CPSC) had jurisdiction to consider the promulgation of a rule banning high tar cigarettes from interstate commerce. S. Rep. No. 94-251, 94th Cong., 2d Sess. 5 (1976). See also the letter from Elmer B. Staats, Comptroller General, to the Hon. Sam J. Ervin, Jr., Chairman, Senate Committee on Government Operations, 120 Cong. Rec. S. 6225, 6227 (daily ed. April 24, 1974), advising that, although the definition of "hazardous substance" might literally include tobacco products, the FCLAA and its amendments "preempt the field of cigarette smoking and its relation to health."

For the above reasons, FDA is denying your request to assert jurisdiction over cigarettes containing nicotine as "devices" under the Act.

II. Attached Cigarette Filters.

Petition No. 2 requests that FDA recognize jurisdiction over attached cigarette filters, which ASH describes as an "integral part of many brands of cigarette" (p. 6), as "devices" under section 201(h)(2) of the Act. For the reasons discussed below, we are denying this request.

ASH asserts that the manufacturers of cigarettes are making implied claims that bring attached filters within the definition of device. Petition No. 2 provides examples of filter cigarette labeling and advertising, all of which include representations as to the level of tar, nicotine, or other constituents of cigarettes or of cigarette smoke. ASH contends (Petition No. 2, p. 3) that "... cigarette filters which are designed and sold to remove tar, nicotine or harmful gases from tobacco smoke fall squarely within th[e] literal language" of the statutory definition of "device". In addition, ASH asserts that "cigarette manufacturers are using a wide variety of filters, and each is making express or implied claims that the use of its filter will mitigate, treat or prevent smoking-related diseases by removing the 'tar,' nicotine or gases from the tobacco smoke" (Petition No. 2, p. 14).

In this connection, we have also reviewed the cigarette advertisements presented to the Anesthesiology Device Section of the Respiratory and Nervous System Devices Panel (formerly the Anesthesiology Device Classification Panel). In addition,

we have considered the transcript of the Panel's deliberations concerning cigarette filters and the conclusion of the Panel that attached cigarette filters are "devices." We do not agree with the Panel's assessment of advertisements for filtered cigarettes and find that the advertisements presented to the Panel are of the same nature as the filter cigarette advertisements attached to Petition No. 2.

Representations in cigarette labeling or advertising of the nature of those in the record of Petition No. 2 as to the absolute or relative quantity of hazardous constituents of cigarette smoke or as to the safety of the cigarettes do not make the cigarettes or their filters intended for use in the mitigation, treatment, or prevention of disease.

The representations in the filtered cigarette labeling and advertising in Petition No. 2 are made in the context of long-standing public discussion of potential health hazards of smoking and, in recent years, of warnings which have been statutorily required on cigarette packages. ASH provided in Petition No. 2 as "good examples" (p. 11) of implied claims a series of advertisements (Exhibits H-O) (see also pp. 11-14 and Exhibits P-W). ASH itself admits that the advertisements do not imply that there is a health benefit for which purpose the filter cigarettes should be used, absent the desire to smoke (p. 12; see also Petition No. 1, p. 34).

Where, as here, attached filters are at most represented as making the cigarettes to which they are attached less hazardous to smoke, neither the cigarettes nor the filters are thereby intended for use in the mitigation, treatment, or prevention of disease.

FDA or its employees may have previously responded in a different manner to inquiries about cigarettes. FDA's position concerning representations of the types discussed above for cigarettes with attached filters is set forth herein and any inconsistent prior statements or opinions issued by or on behalf of FDA or any of its employees are hereby rescinded.

ASH asserts that objective evidence other than manufacturers' claims can be material to a determination of intended use under the statutory definition, and that National Nutritional Foods Ass'n v. Food and Drug Administration, 504 F.2d 761 (2d Cir. 1974), cert. denied, 420 U.S. 946 (1975), is authority for this interpretation (Petition No. 2, p. 21). We agree. However, the court there held that the vendor's intent is the crucial element in the statutory definition and that objective evidence sufficient to pierce the manufacturer's subjective claims must be presented (504 F.2d at 789).

As Petition No. 2 also discusses, in National Nutritional Foods Ass'n v. Weinberger, 512 F.2d 688 (2d Cir. 1975), the court indicated that a finding that the product was used by consumers almost exclusively for therapeutic purposes could support a determination that the product was intended for use in the cure, mitigation, prevention, or treatment of disease (512 F.2d at 703). In National Nutritional Foods Ass'n v. Mathews, 557 F.2d 325 (2d Cir. 1977), the court reiterated that vendor intent in selling a product to the public is the key element in the statutory definition (557 F.2d at 333). Those cases support FDA's position that it is the intent of the manufacturers or vendors that objective evidence must establish and that evidence of consumer use can be one element of objective evidence to be weighed in determining if the intended purpose of a product subjects it to regulation under the Act. ASH has not established that consumers use attached cigarette filters for the prevention, mitigation, or treatment of disease to the extent necessary to allow FDA to impute the requisite intended uses to manufacturers or vendors.

The evidence presented in Petition No. 2 concerning consumer intent regarding attached filters establishes at most that many consumers may regard attached filters as reducing exposure to hazardous constituents of cigarettes and creating a "safer" cigarette. As noted above, this will not bring attached filters within the definition of "device".

Because attached filters are necessarily used with the cigarettes of which they are constituent parts, the intent of consumers in using attached filters is reasonably understood and assessed together with consumer intent with respect to filtered cigarettes. ASH has not asserted that cigarettes with filters are intended to prevent, mitigate, or treat disease. Petition No. 1 expressly disclaims reliance on such an assertion when it discusses FTC v. Liggett & Myers Tobacco Co., 180 F. Supp. 573 (S.D.N.Y. 1952), aff'd, 203 F.2d 955 (2d Cir. 1953). Petition No. 1 characterizes as "tenuous" the very line of reasoning that Petition No. 2 relies upon in asserting that attached cigarette filters are intended to mitigate, treat, or prevent disease (Petition No. 1, p. 17).

We have also considered ASH's arguments concerning the intent of researchers, and find that the material in Petition No. 2 concerning that intent does not lead to different conclusions than does the evidence of consumer intent regarding attached filters.

For these reasons, FDA is denying your request to assert jurisdiction over attached filters as "devices" under the Act. We believe that congressional consideration of cigarettes included filter cigarettes and, as discussed in Section I, supports our conclusion that attached filters, as customarily marketed, are not within FDA's jurisdiction.

III. Detached Filters

ASH contends that detached filters, which are purchased separately from cigarettes and "installed by the smoker on the end of the cigarette" (Petition No. 2, p. 6), are subject to FDA's jurisdiction because:

1. Detached filters are advertised as useful in the mitigation, treatment, or prevention of disease (p. 6); or
2. Detached filters are advertised as useful aids in efforts to stop smoking and, therefore, are articles intended to affect the structure or function of the body or to mitigate, treat, or prevent disease (p. 8); or
3. Consumers use detached filters intending to mitigate, treat, or prevent disease (p. 16).

For the reasons stated below, the requests in Petition No. 2 with respect to detached filters are granted in part and denied in part.

We have reviewed the labeling and advertising submitted in Petition No. 2 concerning detached filters to determine whether representations for these products establish that detached filters are intended to be used to mitigate, treat, or prevent disease or to affect the structure or function of the body. We agree that some of that labeling and advertising establishes that manufacturers of certain detached filters, i.e., One Step At A Time, Venturi, and Nu Life Smokers Kit, have made representations that would bring these products under the device definition and, thus, FDA's jurisdiction.

The labeling and advertising submitted for other detached filters, i.e., Aquafilter and Medico Charcoal Filters, do not establish that these products are intended for a purpose that would bring them within the definition of device.

We would point out that all of the detached filters for which labeling and advertising were submitted in Petition No. 2 are intended to reduce the amount of tar, nicotine, or gases inhaled by the smoker or to aid the smoker to reduce or stop smoking. This does not establish manufacturer intent to

mitigate, treat, or prevent disease, or to affect the structure or function of the body. As noted in Section II, we do not agree with the assertion in Petition No. 2 that "cigarette filters which are designed and sold to remove tar, nicotine or harmful gases from tobacco smoke" fall squarely within the literal definition of "device." Manufacturers of detached filters which are intended to remove tar, nicotine, and gases or to aid the smoker to reduce or stop smoking may be responding to consumer demand for a low tar, low nicotine, low gas cigarette, or a stop smoking aid to enable them to reduce the costs of smoking or eliminate the odor associated with smoking, etc. Only if detached filters intended for these purposes are coupled with other evidence that, when viewed together, establish the requisite intended use, will the products come within FDA's jurisdiction.

As noted in Section II, a claim of general or comparative safety, without more, will not usually cause a product to be subject to the Act. Many products are designed and sold to be used to reduce the exposure of humans to hazardous substances. For example, catalytic convertors and lead-free gasoline for use with automobiles are designed to reduce the exposure of humans to lead and hazardous by-products of gasoline combustion. These products, however, are not deemed to be within the Agency's jurisdiction. The determination that a product is properly regulated under the Act is not left to FDA's unbridled discretion but must be in accordance with the statutory definition. United States v. 62 Cases of Jam, 340 U.S. 593 (1950).

ASH's contention that consumer use of (or researchers' intent with respect to) detached filters brings these products within FDA's jurisdiction is identical to petitioner's discussion of attached filters. Our position is the same as discussed under Section II of this letter, as supplemented by our discussion above of evidence of intended use.

Therefore, Petition No. 2 has not provided evidence establishing FDA's jurisdiction over all detached filters. As stated above, we have concluded that FDA has jurisdiction over particular detached filters for which the evidence of the requisite intended use has been shown in Petition No. 2. The evidence in Petition No. 2 has also established that detached filters have been marketed with labeling and advertising which do not provide evidence of the requisite intended use.

FDA may have previously responded to inquiries regarding detached cigarette filters intended to aid the smoker to reduce or stop smoking. As noted under Section II with respect to attached filters, this response sets forth FDA's position and rescinds any earlier correspondence or opinions concerning detached filters that may be in conflict.

IV. Rulemaking

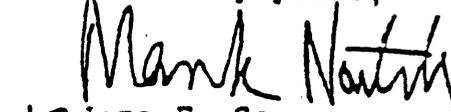
ASH has requested that FDA commence rulemaking proceedings to establish the means by which FDA should exercise its jurisdiction over cigarettes and attached and detached filters as medical devices. In the FEDERAL REGISTER of November 2, 1979, FDA stated that it was not issuing a proposed regulation to classify cigarette filters pending action on ASH's petition (44 FR 63292 at 63299). ASH's request to commence rulemaking is granted in part and denied in part.

Insofar as rulemaking would relate to cigarettes or attached filters as customarily marketed, we have concluded that FDA has no jurisdiction under section 201(h) of the Act. Therefore, no rulemaking is permissible as a matter of law.

Insofar as rulemaking would relate to detached filters, we have concluded that FDA has jurisdiction under section 201(h) of the Act over some, but not all, detached filters. We are granting your request that FDA institute rulemaking with respect to those detached filters over which FDA has jurisdiction.

In accordance with 21 CFR Part 860, FDA will propose to classify detached filters that are medical devices. FDA currently does not intend to institute other rulemaking proceedings specifically for these detached filters. However, rulemaking that FDA institutes with respect to other articles may also be applicable to detached filters that are devices.

Sincerely yours,



Jere E. Goyan
Commissioner of Food and Drugs