Appendix 6

Citizen Petitions and Submitted comments

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The document to which this appendix is attached explains that the legal analysis and record before the Food and Drug Administration demonstrate that nicotine-containing cigarettes and smokeless tobacco products meet the definition of drugs and devices under the Federal Food, Drug, and Cosmetic Act (the Act) because they are intended to affect the structure or function of the human body. The Coalition on Smoking OR Health (Coalition) and Action on Smoking and Health (ASH) have each submitted citizen petitions asking FDA to regulate cigarettes under the Act. See In re Cigarettes Containing Nicotine, No. 94P-0077 (Mar. 4, 1994) and Petition of the American Heart Association, No. 94P-0069 (Mar. 7, 1994).

The petition submitted by the Coalition urged FDA to regulate cigarettes containing nicotine as drugs because they are intended to affect the structure or function of the body within the meaning of section 201(g)(1)(C) of the Act and because low-tar and low-nicotine products are intended to mitigate or prevent disease within the meaning of section 201(g)(1)(B) of the Act. The petition submitted by ASH urged FDA to assert jurisdiction over cigarettes containing nicotine and to impose appropriate regulatory restrictions through administrative rulemaking.

In its citizen petition, ASH requested that the FDA commence rulemaking to determine that nicotine is a drug, or that cigarettes are drug delivery systems, and therefore subject to FDA's jurisdiction. In re Cigarettes Containing Nicotine, No. 94P-0077 (Mar. 4, 1994). ASH argued that the threshold inquiry as to whether FDA has jurisdiction over these products required FDA's special expertise to resolve. ASH urged FDA to commence rulemaking proceedings at its earliest convenience because of the numerous smoking-related fatalities, the astronomical

medical costs associated with smoking, and the number of children that continue to be attracted to cigarettes and smokeless tobacco products, many of whom will become addicted to nicotine. ASH filed a second petition and notice of intent to sue on December 22, 1994, reiterating some of these same points.

The Coalition filed a similar petition on March 7, 1994. Petition of the American Heart Association, No. 94P-0069 (Mar. 7, 1994). The Coalition argued that cigarettes should be regulated as drugs under the Act because nicotine is addictive, the cigarette manufacturers are aware that nicotine is addictive, and the manufacturers intentionally manipulate nicotine levels to maintain addiction, and because cigarettes advertised as low-tar and low-nicotine are intended to mitigate or prevent disease.

FDA has received numerous comments on these citizen petitions to date. Illustrative comments are discussed briefly below. The record on these petitions remains open.

Two cigarette manufacturers, Philip Morris ("PM") and R.J. Reynolds Tobacco ("RJR") filed responses to the petitions on September 6 and November 2, 1994, respectively. PM and RJR argue that only Congress can regulate cigarettes, but the arguments are devoid of any authority that directly supports that proposition. FDA's responsibilities include the determination of whether a product is subject to the Act and, if so, under what provision, e.g., whether tobacco products are drugs or devices. See Legal Analysis of Jurisdiction at p. 2.

PM and RJR also asserted that FDA in the past has stated that FDA lacks jurisdiction over cigarettes where no therapeutic claims are made. As described in the attached document, the statutory definition of drug includes two parts: the term "drug" is defined, in relevant part, as an article "intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease"

or an article "intended to affect the structure or any function of the body." 21 U.S.C. § 321(g)(1)(B), (C). At the time that earlier determinations were made, there was little or no evidence that cigarettes and smokeless tobacco products were intended to affect the structure or function of the body. In the absence of therapeutic claims, therefore, there was no basis to conclude that cigarettes and smokeless tobacco products were drugs. As discussed in the determination of jurisdiction, the evidence today regarding tobacco manufacturers' intent to affect the structure or function of the body is substantial and far greater than at any time in the past. See Legal Analysis of Jurisdiction, § II.B. and Findings. FDA has provided a reasonable explanation for its current position and therefore is justified in modifying its former position. See Legal Analysis of Jurisdiction at p. 21, n.5.

PM and RJR also asserted that objective intent can only be shown through evidence of manufacturers' express therapeutic claims made in connection with a sale of the product. As discussed in the document setting forth FDA's legal analysis, FDA does not believe that such position is or should be the current state of the law. Evidence of intended use can be derived from a variety of sources, not simply manufacturers' carefully controlled sales claims. See Legal Analysis of Jurisdiction, § II.A.

RJR and PM have also made a series of evidentiary arguments. They have asserted that there has been no significant change in the evidence since ASH. As discussed above, FDA believes based on the record before it that the evidence has changed significantly since that decision. RJR and PM also argued that many categories of evidence -- such as evidence on addiction, manufacturing processes, industry research, patents, consumer use, and statements by

tobacco company executives -- are irrelevant to intended use. As the foregoing document explains, FDA believes that such evidence is relevant. See id.

PM also urged FDA to reject current definitions of addiction used by established medical organizations because they "lack any scientific significance." Comments of Philip Morris U.S.A. at 18. FDA strongly disagrees. FDA believes that it is more appropriate to use current definitions than outdated ones. See Findings, § I.B.

FDA has received thousands of additional comments from interested members of the public -- both for and against regulating of tobacco. Among those comments from those opposed to regulating of tobacco, there are several recurring themes. First, many assert that regulation of tobacco would interfere with an adult smoker's freedom to choose whether to smoke. This view appears to be the result of a misperception that regulation will necessarily lead to a ban on cigarette sales. There are several other possible regulatory actions that could be taken, such as requiring purchasers of tobacco products to show proof of age. Second, some comments express a belief that tobacco is overregulated because it is subject to regulation by several federal agencies and at state and local levels. However, current regulatory schemes are not reducing the number of children and teenagers who are becoming addicted to tobacco products. FDA believes that regulation is necessary to address that problem. Third, some comments assert that the Agency's resources are better spent on ensuring the safety of the nation's foods and drugs. FDA believes that nicotine-containing tobacco products constitute the leading public health risk today and warrant FDA's attention. Fourth, some comments asserted that FDA's view of tobacco was a minority view not shared by the majority of Americans. FDA has not received, and is not aware of, any credible evidence that would support that assertion.

Other comments have favored the regulation of nicotine-containing tobacco products. Some comments focus on the costs -- both financial and human -- associated with smoking-related diseases. Other comments express concern over the availability of cigarettes to children and teenagers. Comments have also been received from individuals who have lost a friend or family member to a smoking-related disease and from former smokers who had difficulty quitting or suffered adverse health effects from smoking. FDA shares these concerns.