Appendix 10

Additional Documents

APPENDIX 10

ADDITIONAL DOCUMENTS

In addition to the documents cited in the accompanying jurisdiction document, FDA has obtained a significant quantity of internal documents from a major U.S. tobacco company that provide further evidence to support FDA's determination that nicotine in cigarettes and smokeless tobacco products is a drug and that these products are nicotine delivery devices under the Federal Food, Drug, and Cosmetic Act ("the Act") and subject to FDA's jurisdiction. FDA has analyzed these documents and determined that, while not necessary to the agency's conclusion that cigarettes and smokeless tobacco products fall within the agency's jurisdiction, the documents are entirely consistent with that conclusion. The documents contain evidence relevant to each of the areas enumerated in the factual findings supporting the agency's analysis of its jurisdiction over these products, including:

- statements by officials of this company that nicotine's pharmacological effects are essential to tobacco use, and that nicotine has the properties associated with addictive drugs;
- evidence that the company has conducted and funded research on the effects of nicotine on the brain as well as research establishing that nicotine has the properties of an addictive drug;
- evidence that the company has conducted research to establish the dose of nicotine

necessary to satisfy consumers;

- evidence that the company has conducted research on the tendency of smokers to compensate for changes in nicotine delivery;
- evidence that the company has conducted product development research focused on establishing the optimum nicotine delivery and the optimum nicotine/tar ratio in cigarettes, and that this research frequently involved adding nicotine to experimental cigarettes;
- evidence that the company increased the nicotine/tar ratio in some of its products;
- evidence that the company has conducted research on nicotine analogues intended to produce a compound with the same psychoactive effects as nicotine but without its adverse effects; and
- evidence that, in the course of developing alternative tobacco products, the company took steps to ensure that the products would contain an adequate dose of nicotine.

FDA has reason to believe that these documents may have originally been produced in litigation and may be subject to a protective order. Because of the possibility that the documents may be subject to a protective order, FDA does not believe that the documents should be made public until their status under any applicable protective order can be resolved. FDA has compiled a confidential list of these documents with a brief description of their relevance to the agency's analysis of its jurisdiction over tobacco products.

On July 25, 1995, several of the documents included among those referred to in Appendix 10 were entered into the Congressional Record by Congressman Waxman (D-Cal),

without objection. FDA has concluded that there is no bar to use of the specific documents that were publicly disclosed documents.