MEMBER OF.

COMMITTEE ON FNEHGY
AND COMMERCE

COMMITTEE ON FNE DISTRICTI
OF COLUMBIA

Congress of the United States

House of Representatives Washington, DC 20515-4607

March 18, 1994

WASHINGTON OFFICE: 2241:RAYSURN OFFICE BUILDING (202):225-2818

DISTRICT OFFICES

3UPF 101 4934 FIZHUGH AVENUE RICHMOND, VA. 23230-3534 (BO4):774-2809 1-4800-438-3783

CULPLPLR OFFICE PARK SUITE 207 783 MADISON ROAD CULPEPER, VA 22701-2343 (703) 828-8880

The Honorable David A. Kessler Commissioner Food and Drug Administration 5600 Fishers Lane Room 14-71 Rockville, Maryland 20857

Dear Dr. Kessler:

Your correspondence of February 25, 1994 to Scott D. Ballin, Chairman of the Coalition on Smoking OR Health, contained disturbing allegations concerning the intent of cigarette manufacturers with respect to the role of nicotine in cigarettes.

Specifically, your letter stated, "Evidence brought to our attention is accumulating that suggests that cigarette manufacturers may intend that their products contain nicotine to satisfy an addiction on the part of some of their customers. The possible inference that cigarette vendors intend to achieve drug effects in some smokers is based on mounting evidence we have received that: (1) the nicotine ingredient in cigarettes is a powerfully addictive agent and (2) cigarette vendors control the levels of nicotine that satisfy this addiction."

As these are serious charges likely to be addressed before a Congressional hearing on March 25. I request that you provide the following information and documents to my office prior to the hearing.

- (1) All "evidence" in the FDA's possession "that suggests that cigarette manufacturers may intend that their products contain nicotine to satisfy an addiction on the part of some of their customers," along with
 - (a) a written summary of such "evidence" if it was given orally to the FDA; and
 - (b) copies of any and all documents given to the FDA in connection with this allegation; and
 - (c) the names, addresses and titles of all individuals and organizations from whom you received evidence in

connection with this allegation.

- (3) All "evidence" in the FDA's possession that "manufacturers commonly add nicotine to deliver specific amounts of nicotine," along with
 - (a) a written summary of such "evidence" if it was given orally to the FDA; and
 - (b) copies of any and all documents given to the FDA in connection with this allegation; and
 - (c) the names, addresses and titles of all individuals and organizations from whom you received evidence in connection with this allegation.
- (3) All "evidence" in the FDA's possession supporting your statement that "There is also evidence discovered in recent litigation that some of the individuals involved in the manufacture of cigarettes in the 1970s regarded their products as nicotine-delivery systems," along with
 - (a) a written summary of such "evidence" if given orally to the FDA; and
 - (b) copies of any and all documents given to the FDA in connection with this matter; and
 - (c) the names, addresses and titles of all individuals and organizations from whom you received evidence in connection with this allegation.
- (4) All other "information" or "evidence" brought to the FDA's attention or otherwise received by the FDA that you relied on to support the statements made in your February 25 letter to Mr. Ballin regarding the intent of cigarette manufacturers concerning nicotine*. In addition, please indicate whether you received any or all of the "information" or "evidence" before or after your February 25 letter was released.

Please provide this information to my office no later than March 21, 1994.

Sincerely,

Thomas J. Bliley, Jr.

2023898696