

OCT 26 1988

The Honorable Christopher H. Smith
House of Representatives
Washington, D.C. 20515

Dear Mr. Smith:

This is in response to your inquiry of September 20, 1988, on behalf of Mr. Seymour V. Lipkowitz, Marlboro, New Jersey, about speeding the availability of new drugs for the treatment of life-threatening and severely-debilitating illnesses.

As you may know, on October 19, the Food and Drug Administration (FDA) announced procedures designed to reduce the time required for human testing of such drugs, while preserving appropriate guarantees of safety and effectiveness. A key component of these procedures is early consultation between FDA and drug sponsors in order to reach agreements on the most time-efficient animal and human studies necessary to answer safety and efficacy questions. It is hoped that, through this cooperation, properly designed phase 2 controlled clinical trials could eliminate the need for extensive phase 3 studies to provide adequate data to support approval.

We are enclosing a copy of an HHS news release which contains more detailed information and a copy of the interim rule as published in the Federal Register on October 21 for your information.

If we can be of any further assistance, please let us know.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

Enclosures

cc: HFW-10(2)
R/D: JCMarrone:10/20/88
R/T: cah:10/20/88 & 10/21/88
Edit: WMara:10/24/88
F/T: cah:10/24/88 (JOANNE--AVAIL/DRUGS)

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CHRISTOPHER H. SMITH



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Washington, DC 20515

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September 20, 1988

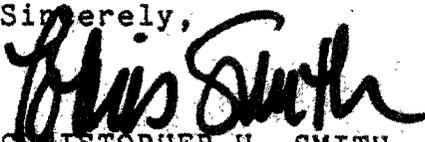
Hugh C. Cannon
Food and Drug Administration
Office of Legislative Affairs
1555 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Dear Mr. Cannon:

Enclosed, please find a copy of a letter from one of my constituents, Seymour Lipkowitz, regarding FDA's proposal to lift the "phase three" efficiency tests for certain new drugs.

As you will note from the enclosure, Mr. Lipkowitz supports a relaxation of the approval process for new drugs. Could you please provide me with information as to the status of this proposal and other relevant information?

Thank you for your cooperation in this matter. I look forward to receiving your reply.

Sincerely,

CHRISTOPHER H. SMITH
Member of Congress

CHS/emw
enclosure

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