DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 25 1999

6107 '99 JUL -2 P1:57

Joseph Mendelson III
Legal Director
International Center for Technology Assessment
310 D Street NE
Washington, DC 20002

Dear Mr. Mendelson, III:

On June 16 you wrote the Commissioner, Food and Drug Administration, expressing a concern about Agency inaction in responding to Citizen Petition Docket No. 98P-1194. I am responding to your letter on behalf of the Commissioner and providing you a tentative response to your Citizen Petition as permitted under 21 CFR 10.30(e)(2)(iii).

Your Citizen Petition (CP) was submitted on December 15, 1998, and amended on January 20, 1999.

I can advise that CP 98P-1194 is under active evaluation and that we expect to issue a final response within a few weeks. However, because of the complex nature of the action requested, which requires careful and thorough scientific, legal, and policy consultation, analysis, and coordination, FDA will require additional time beyond July 20 to issue a final response to your CP.

Sincerely yours,

Stephen F. Sundlof, D.V.M., Ph.D.
Director, Center for Veterinary Medicine

cc:
HF-40 (99-4143)
HFA-340 (Docket # 98P-1194)
HFV-1 (OD#37) (2)
HFV-6
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98P-1194

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16 June 1999

Commissioner Jane Henney
Food and Drug Administration
Parklawn Building, Room 1471
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner Henny:

Pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. § 553(e), and the FDA implementing regulations, numerous organizations have petitioned your office to take action regarding, *inter alia*, the potential human and animal health impacts associated with the animal drug bovine growth hormone ("rBGH or rBST"). See FDA Docket No. 98P-1194. More specifically, the agency has been requested to initiate procedures to withdraw the approval of Posilac®. Since the filing of the petitions over six months ago, your office has failed take any action concerning the issues presented by the International Center for Technology Assessment and other petitioners. The agency's failure to respond to the citizen petition denies petitioners relief at the agency level and is a constructive denial of the petitioner's request. As such, petitioners intend to pursue other avenues, including judicial review, in order to assure that the agency responds to the issues raised by the CTA.

Indeed, the agency inaction in this matter is subject to judicial review. Under the APA "agency action" is defined to include "the whole or part of an agency rule, order, license, sanction, relief, or the equivalent denial thereof, *or failure to act*"[1] and gives courts the power to "compel agency action unlawfully withheld or unreasonably delayed."[2] Thus, the APA authorizes courts to review agency decisions to refrain from taking action.[3] When administrative inaction has precisely the same impact on the rights of the parties as denial of relief, an agency cannot preclude judicial review by casting its decision in the form of inaction rather than in the form of an order denying relief.[4]

In addition, the agency's inaction is violative of established agency regulations. The FDA has established regulations in which a reasonable period for agency response to citizen petitions can be

[1] 5 U.S.C. § 551(13) (1995) (emphasis added).

[2] 5 U.S.C. § 706(1) (1995).

[3] Chaney v. Heckler, 718 F.2d 1174, 1183, n. 22 (D.C. Cir. 1983).

[4] Environmental Defense Fund v. Hardin, 428 F.2d 1093, 1099 (D.C. Cir. 1970).

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no more than 180 days.[5] Regulations which are promulgated by an administrative agency in carrying out it statutory mandate can also provide standards for judicial review of agency action.[6] Such self-imposed constraints may supply the "law to apply" to overcome the judicial presumption against reviewing administrative inaction.[7] Thus, the agency must act in a "prompt" manner or be subject to further action. The agency's delay in answering the current petitions amounts to a refusal to act, with sufficient finality and ripeness to permit judicial review.[8]

Furthermore, petitioners remind the FDA that excessive and unreasonable delay in addressing matters brought to its attention by the public saps the public confidence in an agency's ability to discharge its responsibilities and creates uncertainty for the parties, who must incorporate the potential effect of possible agency decision making in the future.[9]

Petitioners request the agency to respond to the aforementioned petition within fourteen (14) calendar days. In the absence of an affirmative response, the petitioners will be compelled to consider litigation in order to achieve the full and complete action required to address this violation of federal law.

Sincerely,

Joseph Mendelson, III
Legal Director

CC: Docket No. 98P-1194
Dockets Management Branch
F.D.A.
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

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[5] 21 CFR § 10.30(e)(2) (1998).

[6] Center for Auto Safety v. Dole, 846 F.2d 1532, 1534 (D.C. Cir. 1988).

[7] Center for Auto Safety v. Dole, 846 F.2d 1532, 1534 (D.C. Cir. 1988).

[8] EDF v. Hardin, 428 F.2d at 1100.

[9] Public Citizen Health Research Group v. Food and Drug Administration, 740 F.2d 21, 32 (D.C. Cir. 1984) *quoting* Potomac Electric Power Co. v. ICC, 702 F.2d 1026, 1034 (D.C. Cir. 1983).

99-4143