

ROUTING SLIP
GENERATED BY: HF-40
DATE: OCT 25,2002

FDA CONTROL NUMBER: 02 5404

TRACER # OS #

DATE OF CORRESPONDENCE: 10/15/02

DATE INTO FDA: 10/25/02

TO: LESTER M CRAWFORD HF-1

FROM: JOSEPH MENDELSON, III, CFS, THE CENTER FOR FOOD SAFETY

SYNOPSIS: DEMANDS THAT FDA RECTIFY ITS ALLEGED UNREASONABLE DELAY IN PROVIDING THE CENTER FOR FOOD SAFETY (CFS) WITH A "SUBSTANTIVE" ANSWER TO PETITION RE: GENETICALLY ENGINEERED FOODS; DOCKET NO. 00-1211; CC: J. LEVITT, DOCKETS (REF: 01-5867, 02-2213).

LEAD OFFICE: HFA-305

HOME OFFICE: HF-40

CONTACT/PHONE#: KELLY M MALONE 301-827-4437

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GCF-1

COORDINATION:

SIGNATURE REQUIRED:

REFERRALS FROM HF-40

ASSIGNED TO	ACTION	DUE DATE
----- HFA-305 BUTLERJ	----- NECESSARY ACTION	-----



THE CENTER FOR FOOD SAFETY

15 October 2002

Dr. Lester Crawford
Deputy Commissioner
Food and Drug Administration
Parklawn Building, Room 1471
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Crawford:

Pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. § 553(e), and the FDA implementing regulations, the Center for Food Safety and numerous other organizations petitioned your office on March 21, 2000, to take action regarding, *inter alia*, the potential human health and environmental impacts associated with the use and commercialization of genetically engineered foods. See FDA Docket No. 00-1211. More specifically, the agency has been requested to initiate new rulemaking to establish mandatory pre-market safety, environmental review and labeling regulations for all genetically engineered crops and foods. Since the filing of the petition well over two years ago, your office has failed to take any action concerning the issues presented by the petitioners. This letter serves as a third, and final, letter demanding that the FDA rectify its unreasonable delay in this matter by providing CFS with a substantive answer to its petition.

As you are well aware, the CFS legal petition has received the public support of several hundred thousand individuals. Coupled with the FDA's statutory obligation to ensure the safety of our country's food supply, the intense public support for mandatory regulatory oversight of genetically engineered foods necessitates your agency's immediate response to the petition. By refusing to act, the FDA continues to deny petitioners and these members of the public 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 petitioners.

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

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

02-5404



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 no more than 180 days.⁵ Regulations which are promulgated by an administrative agency in carrying out its 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

As put before the agency in a December 3, 2001, letter to Acting Principal Deputy Commission Schwetz, and a March 27, 2002, letter to you, petitioners request that the agency adhere to its regulatory procedures and respond to the aforementioned petition. In the absence of an affirmative response by November 15, 2002, 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.

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).

⁵ 21 CFR § 10.30(e)(2) (1998).

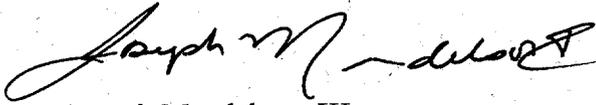
⁶ Center for Auto Safety v. Dole, 846 F.2d 1532, 1534 (D.C. Cir. 1988).

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).

Sincerely,



Joseph Mendelson, III
Legal Director

CC: Joseph A. Levitt
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Docket No. 00-1211P
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