

EXHIBIT C



Food and Drug Administration
Rockville MD 20857

DEC 22 2014

Meredith Berger
Global Health Justice Partnership
Yale Law School
P.O. Box 208215
New Haven, CT 06520

In Reply Refer To: 2014-9958

Dear Requester:

This is in response to your request for expedited processing of your Freedom of Information Act (FOIA) request for information regarding K955168, K000470 and Q131322.

The Electronic Freedom of Information Act (EFOIA) Amendments of 1996 amended the FOIA by adding section (a)(6)(E), 5 U.S.C. 552(a)(6)(E), to require agencies to consider requests for expedited processing and grant them whenever a "compelling need" is shown and in other cases as determined by the agency. The term "compelling need" is defined as (1) involving "an imminent threat to the life or physical safety of an individual," or (2) in the case of a request made by "a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity."

I have determined that your request for expedited processing does not meet the criteria under the FOIA. You have not demonstrated a compelling need that involves an imminent threat to the life or physical safety of an individual. Neither have you demonstrated that there exists an urgency to inform the public concerning actual or alleged Federal Government activity. Therefore, I am denying your request for expedited processing. The responding agency office will process your request in the order in which it was received.

The Department of Health and Human Services' implementing regulations, 45 CFR 5.34, set forth the procedures for you to follow if you decide to appeal this decision not to provide you with the information you requested. Your appeal should be sent within 30 days from the date you receive this letter to the Deputy Agency Chief FOI Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, Parklawn Building, Room 19-01, 5600 Fishers Lane, Rockville, MD 20857.

Sincerely yours,

Sarah Kotler
Acting Director
Division of Freedom of Information