

EXHIBIT 11



Case No. 2023-00558-FOIA-OS

April 20, 2023

Sent via email:

Phanesh Koneru
Exela Pharma Sciences, LLC
jtorchinsky@holtzmanvogel.com

Dear Phanesh Koneru:

This is an interim response to your March 14, 2023, Freedom of Information Act (FOIA) request.

You requested the following: (All records relating to development, drafting, and/or publication of the December Draft Guidance titled Small volume parenteral drug products and pharmacy bulk packages for parenteral nutrition: Aluminum content and labeling recommendations ... (Date Range for Record Search: From 1/1/2021 To 3/14/2023)).

HHS FOIA Office has determined your request for expedited processing does not meet the requirements under the FOIA and HHS implementing regulations and cannot be granted. The FOIA requires an agency expedite processing of a request only when the requester demonstrates a “compelling need.”

Our review indicates you have not clearly demonstrated a “compelling need,” because you have not clearly articulated an imminent threat to the life or physical safety of an individual; and you also have not demonstrated that there is an “urgency to inform the public concerning actual or alleged Federal activity” through a request by one primarily engaged in disseminating information to the public.

The law authorizes us to collect fees for responding to FOIA requests. However, because we are uncertain that applicable fees will exceed our minimum charge (\$25.00), we are not addressing your request for a fee waiver at this time. Nevertheless, if we determine there will be fees associated with processing your request, we will contact you at that time.

The Department of Health and Human Services regulations allows us to recover part of the costs associated with the processing of FOIA requests. It was determined that your request will be processed under the “Commercial” category; therefore, your request may be subject to **duplication fees at .10 cents per page after the first 100 pages of duplication**. We will notify you if it appears that the fees will exceed the limit in which you set.

If you are not satisfied with my action on this request, you may administratively appeal this denial of expedited processing. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency’s decision.

Please mark the correspondence, “Freedom of Information Act Appeal.” Your appeal must be transmitted within 90 days from the date of receipt of this letter to:

William Holzerland
Deputy Agency Chief FOIA Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs
HHS.ACFO@hhs.gov

If you choose to mail your appeal, please clearly mark both the envelope and your letter “Freedom of Information Act Appeal.” The mailing address is: Room 729H, 200 Independence Avenue, SW, Washington, DC 20201. Please note the entire office is working remotely and appeals sent by mail may receive delayed receipt dates.

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, you may contact the HHS FOIA Public Liaison for assistance at:

HHS FOIA/PA Public Liaison
FOI/Privacy Acts Division
Assistant Secretary for Public Affairs (ASPA)
Office of the Secretary (OS)
U.S. Department of Health and Human Services (HHS)
200 Independence Avenue, SW, Suite 729H
Washington, DC 20201

Telephone: (202) 690-7453
Fax: (202) 690-8320
E-mail: HHS_FOIA_Public_Liaison@hhs.gov

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman’s office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is:

Office of Government Information Services
National Archives and Records Administration
8601 Adelphi Road–OGIS
College Park, MD 20740-6001

Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
E-mail: ogis@nara.gov
Fax: 202-741-5769

Sincerely yours,



Arianne Perkins
Director, Initial FOIA Requests
FOI/Privacy Acts Division