August 11, 2023

In Response Refer to File: ***2023-6472***

Elissa Welle
Reuters News
3 Times Square, 19th Floor
New York, NY 10009

Dear Requester,

This letter is in response to your recent electronic Freedom of Information Act submission in which you requested adverse event cases associated with the use of Saxenda & Rybelsus. Your request was received in the Center for Drug Evaluation and Research on July 27, 2023.

As part of FDA's ongoing system modernization efforts, the Food and Drug Administrations' Adverse Event Reporting System (FAERS II) was released on November 10, 2021, and resulted in the following changes to the FOIA case report output:

1. The FOIA Batch Printing Report for Cases is now a single file that may contain Electronic Submissions, MedWatch Reports (i.e., 3500, 3500A and 3500B) or Attachment files presented in ascending order based on Case IDs with the Case IDs in the report listed on the cover page.
2. All cases will appear in one standardized 'Case Report Information' format. Please refer to the Case Information section, eSub data element, to identify the case as either an Electronic Submission (eSub: Y) or a MedWatch Report (eSub: N).
3. If Attachments and original MedWatch Report images are included with a submission, they will be displayed following each case report.
4. All applicable FOIA exemptions, including exemptions to protect personal privacy information, trade secret information and/or confidential commercial information will continue to be cited where information has been withheld (redacted). Please note the gray overlay background previously used to identify redacted portions in the narrative has been replaced with the applicable FOIA exemption with a series of asterisks (e.g., (b)(6)***).

The releasable documents are enclosed. After a thorough review of the responsive records, we have determined that portions of the documents are exempt from disclosure under exemption (b)(6) of the FOIA, 5 U.S.C. § 552, as amended and delineated below:

> Exemption (b)(6) permits the withholding of information which, if released, would constitute a clearly unwarranted invasion of personal privacy. In this case, it was determined that there is no countervailing public interest qualifying under the standard set forth, under exemption (b)(6), to release the personal identifying information of certain third parties.

In determining to withhold such information, FDA considered 5 USC 552(a)(8)(i), when applicable, and whether FDA reasonably foresees that disclosure of such information would harm an interest protected by the relevant exemption(s) and whether disclosure is prohibited by law.

This concludes the response for the Center for Drug Evaluation and Research. If we can be of further assistance to you, please do not hesitate to contact Kia Bazemore at kia.bazemore@fda.hhs.gov.

Sincerely,

Eli Landy -S Digitally signed by Eli Landy -S Date: 2023.08.11 14:47:25 -04'00'

Eli Landy
Lead Regulatory Counsel
Division of Information Disclosure Policy
Office of Regulatory Policy
Center for Drug Evaluation and Research

You have the right to appeal this determination. Your appeal should clearly identify the agency determination that is being appealed. It would be helpful if you provide specific reasons explaining why you believe the agency's adverse determination should be reconsidered. 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.

Your appeal must be mailed within 90 days from the date of this response, to:

Director, Office of the Executive Secretariat
U.S. Food & Drug Administration
5630 Fishers Lane
Room 1050
Rockville, MD 20857

Or emailed within 90 days from the date of this response to FDAFOIA@fda.hhs.gov. Please clearly mark both the envelope and your letter or email "FDA Freedom of Information Act Appeal."

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact Sarah Kotler at 301-796-8976. You may also contact the FDA FOIA Public Liaison for assistance at:

Office of the Executive Secretariat
US Food & Drug Administration
5630 Fishers Lane Room 1050
Rockville, MD 20857
E-mail: FDAFOIA@fda.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

Enclosure: MedWatch Reports