

DEPARTMENT OF HEALTH AND HUMAN SERVICES Pu

Public Health Service

Food and Drug Administration Division of Freedom of Information 5630 Fishers Lane, Room 1035 Rockville, Maryland 20857

April 11, 2023

In Response Refer to File: 2023-2785

CBS NEWS Attn: Alexander Tin 1330 S Fair Street, Apt 1405 Arlington, VA 22202

This is in response to your letter of April 10, 2023, in which you requested adverse events associated with the use of Carboxymethyl Cellulose Sodium drugs. Your request was received in the Center for Drug Evaluation and Research on April 10, 2023.

Please find enclosed a detailed and summary of all adverse events that have been reported and data which summarizes reports of events to the above-mentioned drug(s). This data contains only reports of adverse events which have been entered into a new database called FDA Adverse Event Reporting System (FAERS). This FAERS report may include duplicate reports (e.g., more than one report for the same adverse event).

Charges of \$1.00 (Search \$0, Review \$0, Reproduction \$0, Computer time \$0, CD \$1.00) will be included in a monthly invoice. **DO NOT SEND ANY PAYMENT UNTIL YOU RECEIVE AN INVOICE.**

Another staff member from the Division of Information Disclosure Policy will respond to the remaining portion of your request.

If you are not satisfied with any aspect of the processing and handling of this request, please contact the Division of the Freedom of Information at (301)796-3603. You also have the right to contact:

FDA FOIA Public Liaison Office of the Executive Secretariat 5630 Fishers Lane Room 1050 Rockville, MD 20857 E-mail: FDAFOIA@fda.hhs.gov This concludes the response from the Center for Drug Evaluation and Research

Sincerely,

Andrea Dyson

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