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March 9, 2023

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: Freedom of Information Act (FOIA) Request

Dear Freedom of Information Officer:

Pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, and FDA's FOIA implementing regulations, 21 C.F.R. § 20.40 *et seq*., Phanesh Koneru, Bridget Archer, and Exela Pharma Sciences, LLC (collectively "Requesters") hereby request the following records[1] in FDA's possession on or after January 1, 2021 through the date of production:

> All records relating to development, drafting, and/or publication of the December 2022 Draft Guidance titled *Small Volume Parenteral Drug Products and Pharmacy Bulk Packages for Parenteral Nutrition: Aluminum Content and Labeling Recommendations*, including all records received, reviewed, or considered by FDA (including any Office, Division, or other administrative unit of the Agency, and/or any FDA employees) in connection with the development, drafting, and/or publication of the December Guidance. Please be sure to include all memoranda, briefings, meeting minutes, reports, notes, talking points, opinions, directives, policy statements, and any other records reflecting or memorializing communications relating to the December Guidance both (1) within FDA, including, but not limited to, communications by, within, between, or among the Office of Generic Drugs, the Office of Pharmaceutical Quality, the Division of Hepatology and Nutrition, the Division of Gastroenterology and Inborn Errors Products, and the Division of Pediatrics and Maternal Health, and/or any of their employees; and (2) between or among FDA and any other Federal or State departments or agencies or their administrative units or employees; Congress (including Members of Congress, committees, subcommittees, and/or

[1] "Records," as that term is defined under FOIA (5 U.S.C. § 552(f)(2)), and under applicable case law (*see, e.g.*, *Forsham v. Harris*, 445 U.S. 169, 193 (1980)) include, but are not limited to, written correspondence, memoranda, records kept in electronic format on computers and/or electronic storage devices, email correspondence (whether through .gov email addresses or private third-party services such as Gmail), records of telephone correspondence, records pertaining to in-person meetings, calendar or scheduling entries, videotapes, photographs, computer print-outs, telephone messages, or voicemail messages.

congressional staff); and any non-governmental corporations, companies, partnerships, unincorporated associations, or other entities or individuals.

Because of the time-sensitive nature of this request, Requesters ask that you strictly comply with FOIA's 20-day deadline. *See* 5 U.S.C. § 552(a)(6)(A). Along with our outside counsel, Requesters would be pleased to discuss this request with you if doing so could help facilitate a timely response. Finally, Requesters ask that FDA process this request consistent with the Department of Justice's policy memorandum (directed to the heads of executive departments and agencies) emphasizing the presumption of disclosure under FOIA, as amended by the FOIA Improvement Act of 2016.[2]

Request for Expedited Processing: Requesters (including Dr. Archer, who is a licensed Doctor of Pharmacy, *see* 21 C.F.R. § 20.44(b)) further request that FDA provide expedited processing of this FOIA request. This request qualifies for expedited treatment pursuant to 21 C.F.R. § 20.44 and 5 U.S.C. § 552(a)(6)(E) because the lack of publicly available information regarding aluminum levels in cysteine drug products could "reasonably be expected to pose an imminent threat to the life or physical safety of an individual," 5 U.S.C. § 552(a)(6)(E)(v)(I), including many preterm infants—whose lives depend on using these products, but who may be seriously harmed by exposure to unsafe levels of aluminum contamination in the process.[3]

L-cysteine is a necessity for proper human life functioning. While healthy adults can naturally synthesize small amounts of L-cysteine, certain high-risk patients—including preterm and/or low birth weight infants and patients with severe liver disease—require L-cysteine supplementation by parenteral administration. Aluminum toxicity in the administration of such treatment can cause serious health problems, including bone toxicity, dementia, impaired neurologic development, Alzheimer's disease, and liver disease, among other conditions. Federal regulation of aluminum in these products thus has a direct impact on the health and safety of society's most vulnerable individuals, and the lack of publicly available information concerning aluminum levels in cysteine products "could reasonably be expected to pose an imminent threat to the life or physical safety," *id.*; 21 C.F.R. § 20.44(b), by depriving healthcare professionals of critical information needed to ensure the health and safety of highly vulnerable patients, including preterm infants who require total parenteral nutrition ("TPN") and adult and pediatric patients with severe liver disease who may have impaired enzymatic processes and require TPN. Patients with underlying renal impairment who receive prolonged courses of parenteral nutrition support are at greatest risk of exposure to toxic levels of aluminum from parenteral nutrition. Obtaining the requested records regarding these government activities is necessary to protect the health of these vulnerable individuals.

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[2] Dep't of Justice Office of Information Policy, Memorandum from The Attorney General, March 15, 2022, *available at* https://www.justice.gov/ag/page/file/1483516/download (last visited September 10, 2022).

[3] *See, e.g.*, Mark R. Corkins, "Review finds greatest risk of aluminum exposure is via parenteral nutrition," American Academy of Pediatrics News, Nov. 25, 2019, *available at* https://publications.aap.org/aapnews/news/13404 (last visited Mar. 6, 2023); Mark R. Corkins, Praveen S. Goday, and Ellen S. Rome, "Aluminum Effects in Infants and Children," American Academy of Pediatrics, vol. 144, no. 6 (Dec. 2019), *available at* https://publications.aap.org/pediatrics/article/144/6/e20193148/37901/Aluminum-Effects-in-Infants-and-Children?autologincheck=redirected (last visited Mar. 6, 2023); Heather A. Wier and Robert J. Kuhn, Aluminum Toxicity in Neonatal Parenteral Nutrition: What Can We do?" SAGE Journals, vol 45, no. 1 (Jan. 2012), *available at* https://journals.sagepub.com/doi/10.1345/aph.1Q399 (last visited Mar. 6, 2023).

As required by federal regulation, the undersigned certify that the above information is true and correct to the best of their knowledge and belief.

Search and Processing of Requested Records: Upon receipt of this request, please take all reasonable steps to preserve relevant public records while the request is pending. Please also contact us promptly to provide an estimated date on which you will finish processing this request. Notice is hereby given that the Requesters request an estimation of appropriate fees incurred and assessed for the "document search and duplication" of the agency records responsive to this request if such fees should exceed $250.00. 5 U.S.C. § 552(a)(4)(A)(ii)(III).

Please search for responsive records regardless of format, medium, or physical characteristics. Requesters ask that responsive electronic records be produced electronically in their native file format, if possible, or the format most felicitous to an expedited production. Alternatively, Requesters request that the Records be provided electronically in text-searchable PDF, in the best image quality in FDA's possession, and in separate, Bates-stamped files.

If this FOIA request is denied in whole or in part, please provide the reasons for the denial, pursuant to 5 U.S.C. § 552(a)(6)(A)(i). If it is your position that any portion of the requested records is exempt from disclosure, we request that you provide a *Vaughn* index of those documents. *See Vaughn v. Rosen*, 484 F.2d 820 (D.C. Cir. 1973). As you are aware, a *Vaughn* index must describe each document claimed as exempt with sufficient specificity "to permit a reasoned judgment as to whether the material is actually exempt under FOIA." *Founding Church of Scientology v. Bell*, 603 F.2d 945, 959 (D.C. Cir. 1979). Moreover, the *Vaughn* index must "describe each document or portion thereof withheld, and for each withholding it must discuss the consequences of supplying the sought- after information." *King v. U.S. Dep't of Justice*, 830 F.2d 210, 223–24 (D.C. Cir. 1987).

In the event that some portions of the requested records are properly exempt from disclosure, please disclose any reasonably segregable, non-exempt portions of the requested records. *See* 5 U.S.C. § 552(b). Pursuant to regulation, please clearly delineate any and all redactions in such a manner so that the justification for each redaction is apparent. If it is your position that a document contains non-exempt segments and that those non-exempt segments are so dispersed throughout the documents as to make segregation impossible, please state what portion of the document is non-exempt, and how the material is dispersed through the document. *Mead Data Cent. v. U.S. Dep't of the Air Force*, 455 F.2d 242, 261 (D.C. Cir. 1977). Claims of non-segregability must be made with the same detail as required for claims of exemptions in a *Vaughn* index. If a request is denied in whole, please state specifically that it is not reasonable to segregate portions of the record for release.

For records available in electronic format, please email the documents to jtorchinsky@holtzmanvogel.com. Please send all other requested documents to the attention of:

Holtzman Vogel Baran Torchinsky & Josefiak
Attn: Jason Torchinsky
2300 N. St. NW Ste. 643A
Washington, D.C. 20037

Finally, we reiterate our request that responsive documents be made available as soon as they are located and reviewed *via* a rolling production. Requesters will pay reasonable increased costs incurred to facilitate a rolling production.

If you have any questions about this request, please do not hesitate to contact either me or my counsel.

Phanesh Koneru Digitally signed by Phanesh Koneru Date: 2023.03.09 14:54:34 -05'00'

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