

EXHIBIT 16



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March 19, 2023

Arianne Perkins
Freedom of Information Officer
Department of Health and Human Services (HHS)
Office of the Secretary (OS)
Freedom of Information Act Office
Hubert H. Humphrey Building, Room 729H
200 Independence Avenue, SW
Washington, D.C. 20201

Re: Case No. 2023-00557-FOIA-OS

Ms. Perkins:

I write in response to your March 15, 2023 letter (the "Clarification Letter") requesting additional information with respect to the above-captioned FOIA request (the "Request"). As you know, that Request sought:

1. Any records relating to Abbreviated New Drug Application ("ANDA") 213073, including, to the maximum extent possible, all communications within HHS (including any Office, Division (other than the U.S. Food and Drug Administration ("FDA"))¹, or other administrative unit of the Department, and/or any HHS employees), and by or between HHS (including any Office, Division (other than FDA), or other administrative unit of the Department, and/or any HHS employees) and the sponsor of ANDA 213073 (Nivagen Pharmaceuticals), regarding aluminum content (including aluminum concentrations, aluminum acceptance criteria and/or aluminum limits).
2. Any records relating to Abbreviated New Drug Application ("ANDA") 214082, including, to the maximum extent possible, all communications within HHS (including any Office, Division (other than FDA), or other administrative unit of the Department, and/or any HHS employees), and by or between HHS (including any Office, Division (other than FDA), or other administrative unit of the Department, and/or any HHS employees) and the sponsor of ANDA 214082 (Eton Pharmaceuticals), regarding aluminum content (including aluminum concentrations, aluminum acceptance criteria and/or aluminum limits).

¹ Requesters have filed separate FOIA requests directly with FDA and therefore do not need HHS to search FDA's records for responsive documents.

3. Any records relating to Abbreviated New Drug Application (“ANDA”) 209994, including, to the maximum extent possible, all communications within HHS (including any Office, Division (other than FDA), or other administrative unit of the Department, and/or any HHS employees), and by or between HHS (including any Office, Division (other than FDA), or other administrative unit of the Department, and/or any HHS employees), and the sponsor of ANDA 209994 (Sandoz) regarding aluminum content (including aluminum concentrations, aluminum acceptance criteria and/or aluminum limits).

Request at 1 & n.1. In an effort to facilitate your compliance with FOIA, the Request further observed “that responsive records are most likely to be located within HHS’s Immediate Office of the Secretary, Office of the Assistant Secretary for Health, and Office of the General Counsel.” *Id.* at 2.

Despite the specificity of our Request—which, generally speaking, seeks all records regarding communications within HHS regarding the relevant ANDAs and their aluminum content—the Clarification Letter asserts that the Request did “not describe[] the records with enough specificity” simply because it did not provide the “name of all HHS employees involved and any other individuals (external to HHS if any) involved name and email domains are required.” Clarification Ltr. at 1-2 (all emphases as in original). The Clarification Letter further suggests that HHS’s FOIA regulations *require* us to provide this information as a condition of processing the Request. *Id.* at 1 (“In accordance with Title 45 Code of Federal Regulations Subtitle A, Subpart B – How to Request Records under FOIA, HHS outlined what must be contained in FOIA requests to allow staff to locate requested records with a reasonable amount of effort.”).

Those assertions are incorrect: The cited regulation does not remotely require FOIA requesters to identify each (or any) of the particular individuals who may have been involved in creating certain responsive records (whether as an author or recipient) or to supply any of the additional information you have demanded.² Instead, the cited regulation merely identifies certain kinds of “[i]nformation *that will help us* find the records you are seeking” and then lists as, illustrative examples, “the agencies, offices, *or* individuals involved” and the “author, recipient, case number, file designation, or other reference number, *if available.*” 45 C.F.R. § 5.22(a)(1), (4) (both emphases added). The Clarification Letter’s assertion that this regulation somehow “require[s]” Requesters to provide the information you have demanded therefore is triply flawed.

First, the courts have held that substantially similar FOIA regulations—which merely identify useful categories of information that would be helpful to the processing federal agency—do *not* in fact require FOIA requesters to supply all (or indeed any) such information as a condition of

² We note that the only concerns your response articulates relate to email searches. Clarification Letter at 2 (demanding that Requesters provide “email domain names”); *id.* (complaining that “HHS cannot run a blind search against all users in HHS or an operating/staff division” because “our live email system ... would crash”); *id.* (seeking domain name information “so that we could identify emails to or from a custodian to those entities”). But the Request is not limited to emails; it seeks “*All records* containing or reflecting communications” between HHS and outside parties regarding the specified subject matter, Request at 1 (emphasis added)—some of which may be contained in emails, and some of which may be contained in other Department records. *Id.* at 1 n.1 (defining the term “records”). You therefore have provided no basis for refusing to commence a search of your other systems for responsive records, and Requesters accordingly reject the Clarification Letter’s assertion that the deadline for responding to this Request has been, or legitimately can be, “tolled.” *Cf.* Clarification Letter at 2.

processing a FOIA request. *See, e.g., Bear v. Attorney General of the United States*, 905 F.3d 151, 156 (3d Cir. 2018) (“The government contends that Bear’s request was insufficiently detailed, in part because it failed to suggest specific sections [of the Department of Justice] in which responsive records might be maintained. The text of the regulation does not require that a request contain that information. It states only that a request should contain that information ‘[t]o the extent possible.’”) (discussing 28 C.F.R. § 16.3(b) (“Requesters must describe the records sought in sufficient detail to enable Department personnel to locate them with a reasonable amount of effort. To the extent possible, requesters should include specific information that may assist a component in identifying the requested records, such as the date, title or name, author, recipient, subject matter of the record, case number, file designation, or reference number.”)). HHS’s regulation does not differ materially from the Department of Justice’s: Just like DOJ’s regulation, HHS’s regulation begins by asserting that FOIA requesters must describe “the records you seek in sufficient detail to enable our staff to locate them with a reasonable amount of effort,” and then identifies certain categories of “information that will help us ... if available.” 45 C.F.R. § 5.22(a). It does not, however, *require* FOIA requesters to supply any such information (whether available or not) as a condition of fulfilling the request, just as the courts have made clear that DOJ’s substantially similar regulation includes no such requirement. *See Bear*, 905 F.3d at 156.

Second, the Request fully complied with your regulation in any event. Whether or not the regulation requires Requesters to supply certain categories of information (and it doesn’t, for the reasons we have just explained), the Request did exactly what the regulation expressly authorizes: It specifically identified “the agencies, offices, *or* individuals involved,” 45 C.F.R. § 5.22(a) (emphasis added), by noting “that responsive records are most likely to be located within HHS’s Immediate Office of the Secretary, Office of the Assistant Secretary for Health, and Office of the General Counsel.” Request at 2. Needless to say, each of the identified “Office[s]” is an “office” within the meaning of 45 C.F.R. § 5.22(a). And the regulation’s disjunctive use of the word “*or*” makes clear that FOIA requesters are *not* required to supply the names of all “agencies, offices, *and* individuals involved” (assuming, for the sake of argument, that it requires anything at all). Any one of those alternatives suffices, and the Request supplied them. *See, e.g., In re Espy*, 80 F.3d 501, 505 (D.C. Cir. 1996) (“[A] statute written in the disjunctive is generally construed as setting out separate and distinct alternatives.”); *cf. Loving v. IRS*, 742 F.3d 1013, 1019 (D.C. Cir. 2014) (“[T]he statute uses the conjunctive ‘and’ — not the disjunctive ‘or’ — when listing the various requirements, a strong indication that Congress did not intend the requirements as alternatives.”).

Finally, the cited regulation expressly acknowledges that FOIA requesters may not have the information you are demanding Requesters now provide—here, for instance, the names and email addresses of any and all persons involved in communications that are contained or reflected in the records we have requested—and therefore makes clear that such information can only “help [HHS]” (let alone be required as a condition of processing a given FOIA request) “*if available.*” 45 C.F.R. § 5.22(a)(4) (emphasis added). That commonsense recognition precisely describes this matter. By its plain terms, the Request seeks information about communications to which Exela was not a party. Requesters do not know, and cannot know, every single person at HHS who may have had communications about the Request’s subject matter with outside parties, let alone every single person outside of HHS who may have had communications with HHS about that subject matter. Indeed, the whole point of the Request is to determine *whether* there were such communications, *who* was involved in such communications, and *what* those communications

were. FOIA in turn makes it your responsibility to find that information for us—not force us to divine and disclose the unknowable as a condition of complying with your statutory obligations.

That having been said, Requesters certainly understand that compliance with your FOIA obligations may require you to run a variety of email searches given the alleged limitations of your email system (though we note that is a problem for which Requesters assuredly are not responsible, and which does not otherwise justify HHS’s refusal to process the Request). HHS of course maintains names and contact information for all staff within the identified Offices (for example, in the Immediate Office of the Secretary, Office of the Assistant Secretary for Health, and Office of the General Counsel). And Requesters have no objection to you running individual searches for responsive documents on an employee-by-employee basis if it really is true that your email system is incapable of running searches on a broader basis (again, however, we note that your own FOIA regulation expressly provides that requests can be made, and therefore can be processed, on an agency- or office-wide basis, and not merely on an individual-by-individual basis, *see* 45 C.F.R. § 5.22(a)(1)).

To the extent it would further assist your efforts, ***and without limiting the scope of the Request in any way***, we might suggest your search of emails begin with the following HHS custodians:

1. Xavier Becerra – Xavier.Becerra@hhs.gov
2. Sean McCluskie – Sean.Mccluskie@hhs.gov
3. Angela Ramirez – Angela.Ramirez@hhs.gov
4. Anne Reid – Anne.Reid@fda.hhs.gov
5. Stephen Cha – Stephen.Cha@hhs.gov
6. Karuna Seshasai – Karuna.Seshasai@hhs.gov
7. Elizabeth Gramling – Elizabeth.Gramling@hhs.gov
8. Kashif Syed – TauheedAliKashif.Syed@hrsa.hhs.gov
9. Samuel Bagenstos – Samuel.Bagenstos@hhs.gov
10. Andrea Palm – Andrea.Palm@hhs.gov
11. Angela Botticella – Angela.Botticella@hhs.gov
12. Melanie Egorin – Melanie.Egorin@hhs.gov
13. Rose Sullivan – Rose.Sullivan@hhs.gov
14. Madeline Daly - Madeline.Daly@hhs.gov
15. Kimberly Espinosa - Kimberly.Espinosa@hhs.gov
16. Alex Graf - Alex.Graf@hhs.gov
17. Steven “Jeff” Hild - Jeff.Hild@acf.hhs.gov
18. Peter Rechter – Peter.Rechter@hhs.gov
19. Leslie Zelenko – Leslie.Zelenko@hhs.gov
20. Stacey Arrington – Stacey.Arrington@hhs.gov
21. William Brady – William.Brady@hhs.gov
22. Caitlin Fross – Caitlin.Fross@hhs.gov
23. Syed Mohiuddin – Syed.Mohiuddin@hhs.gov
24. Remi Roberts – Remi.Roberts@hhs.gov
25. Adm. Rachel L. Levine, MD – Rachel.Levine@hhs.gov
26. Sarah Boateng – Sarah.Boateng@hhs.gov
27. Maura Calsyn – Maura.Calsyn@hhs.gov
28. Michael Iademarco – Michael.Iademarco@hhs.gov

29. Mirabelle Adamu – Mirabelle.Adamu@hhs.gov
30. Evan Sturtevant – Evan.Sturtevant@hhs.gov
31. Steven Rush – Steven.Rush@hhs.gov
32. Keian Weld – Keian.Weld1@hhs.gov
33. HHS Counselors – HHS.Counselors@hhs.gov

Please also request that any custodians review personal email addresses for responsive documents.

We also are pleased to provide the following key search terms to help facilitate your identification of records—whether contained in emails or otherwise—that may be responsive to the Request: “aluminum,” “cysteine,” “Nivagen,” “Sandoz,” “Eton,” “Exela,” “small volume parenteral,” and/or “SVP.”

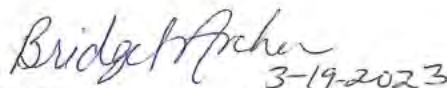
Finally, and as the Request previously noted, Requesters ask that responsive documents be made available as soon as they are located and reviewed *via* a rolling production—a request that is all the more important given that your Clarification Letter raises concerns *only* with respect to HHS’s search of email-based records, and *not* any of the other types of records that might be responsive to the Request. To the extent you continue to have concerns about the email component of the Request after considering this correspondence, we reiterate that there is no lawful basis for refusing to search your other systems/locations for responsive documents and remind you of HHS’s statutory obligation to respond to the Request within 20 days. 5 U.S.C. § 552(a)(6)(A).

If you have further questions about this request, we respectfully suggest that a telephone conference with me and my outside counsel might be the most efficient course of action. Please let me know if and when you would like discuss these issues.

Best regards,

Phanesh Digitally signed by
Phanesh Koneru
Date: 2023.03.19
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3-19-2023

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