UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND
GREENBELT DIVISION

EXELA PHARMA SCIENCES, LLC
1245 Blowing Rock Blvd.
Lenoir, NC 28645

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION,
10903 New Hampshire Ave.
Silver Spring, MD 20993
Montgomery County

Defendant.

Civil Action No.
8:23-cv-0951

COMPLAINT

INTRODUCTION

1. Plaintiff Exela Pharma Sciences, LLC ("Exela" or "Plaintiff") brings this action under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, as amended, challenging the failure of Defendant the Food and Drug Administration (the "FDA" or "Defendant") to respond to and fulfill Exela's FOIA request for records.

2. Exela submitted three FOIA requests to the FDA on March 9, 2023.

3. Exela's first FOIA request seeks documents and records related to the development, drafting, and/or publication of the FDA's interim draft guidance titled *Small Volume Parenteral Drug Products and Pharmacy Bulk Packages for Parenteral Nutrition: Aluminum Content and Labeling Recommendations* (the "December 2022 Draft Guidance"), which proposes to substantially increase the amount of aluminum permitted in cysteine hydrochloride injection products ("FOIA Request One"). Ex. 1.

4. Exela's second FOIA request seeks documents and records related to the submission and review of Abbreviated New Drug Application ("ANDA") 213073, ANDA 214082, and ANDA 209994 by the FDA ("FOIA Request Two"). Ex. 8.

5. Exela's third FOIA request seeks documents and records related to FDA's external communications with Congress and other third parties regarding aluminum content in cysteine drug products ("FOIA Request Three"). Ex. 15.

6. Although more than twenty working days have passed since the FDA acknowledged receipt of each of these three FOIA requests, to date the FDA has not communicated to Exela whether the FDA will fulfill its FOIA requests, nor when Exela can expect its requests to be processed. The FDA has also failed to produce any records to Exela, even though Exela requested that records be made available as soon as they were located via a rolling production. *See, e.g.*, Ex. 1 at 4.

7. Exela accordingly brings this suit to compel FDA to immediately respond to Exela's FOIA requests and promptly disclose all responsive, non-exempt records.

PARTIES

8. Plaintiff Exela is a company existing under the laws of the state of Delaware and authorized to do business in North Carolina, having a principal place of business at 1245 Blowing Rock Blvd., Lenoir, North Carolina 28645. Exela develops, manufactures, and markets sterile injectable pharmaceutical products.

9. Defendant FDA is a component of the U.S. Department of Health and Human Services and is a federal agency within the meaning of the Freedom of Information Act, 5 U.S.C. § 552(f)(1).

LEGAL STANDARD

10. FOIA requires a federal administrative agency to promptly make available requested, non-exempt agency records in response to a request that (a) reasonably describes such records, and (b) "is made in accordance with published rules stating the time, place, fees, . . . and procedures to be followed." 5 U.S.C. § 552(a)(3)(A); *see also* 21 C.F.R. §§ 20.40, 20.41.

11. FOIA requires federal agencies to respond to a valid request within 20 working days (i.e., exempting Saturdays, Sundays, and legal public holidays) after receipt of such request, including notifying the requestor immediately of its determination, the reasons therefore, and the right to appeal any adverse determination. 5 U.S.C. § 552(a)(6)(A)(i); 21 C.F.R. § 20.41.

12. In "unusual circumstances," FOIA allows the 20-day time limit to be extended 10 days by written notice "setting forth the unusual circumstances for such extension and the date on which a determination is expected to be dispatched." 5 U.S.C. § 552(a)(6)(B)(i); *see also* 21 C.F.R. § 20.41(b)(3)(i)(A).

13. If "unusual circumstances" are invoked, the agency must not only provide written notice as detailed above but must also provide the requester "an opportunity to limit the scope of the request so that it may be processed within that time limit or an opportunity to arrange with the agency an alternative time frame for processing the request or a modified request." 5 U.S.C. § 552(a)(6)(B)(ii); *see also* 21 C.F.R. § 20.41(b)(3)(i)(B).

14. "Unusual circumstances" (as used in the context of FOIA) only occur when, to the extent reasonably necessary to the proper processing of the requester's requests, the agency would need to (1) search for and collect records from another facility separate from the office processing the request; (2) search for, collect, and properly examine a voluminous amount of records

demanded in a single request; or (3) consult with another agency to satisfy the request. *See* 5 U.S.C. § 552 (a)(6)(B)(iii); *see also* 21 C.F.R. § 20.41(b)(3)(ii).

15. If the federal agency does not respond to a FOIA request by the statutory deadline, the requester is deemed to have exhausted administrative remedies and may immediately pursue judicial review. 5 U.S.C. § 552(a)(6)(C)(i).

JURISDICTION AND VENUE

16. This Court has jurisdiction under 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. §§ 1331, 2201.

17. Venue lies with this district under 28 U.S.C. § 1391(e)(1) because an agency of the United States is a Defendant, and because this is a district "in which the [requested] agency records are situated," 5 U.S.C. § 552(a)(4)(B). Specifically, the FDA is located at 10903 New Hampshire Avenue, in Silver Spring, Maryland 20993. *See* Food and Drug Administration, "Contact Us," *available at* https://www.fda.gov/about-fda/fda-organization/food-and-drug-administration (last visited Apr. 5, 2023). The FDA's Division of Freedom of Information is located at 5630 Fisher Lane, in Rockville, Maryland 20857.

FACTS

18. Exela is an award-winning specialty pharmaceutical company that develops, manufactures, and markets high-quality pharmaceutical products, with a particular focus on producing generic sterile injectable products for the U.S. market.

19. One particular pharmaceutical product that Exela has developed, manufactured, and marketed is an L-Cysteine injection product used as a nutritional supplement for preterm newborns and infants (together, "neonates") and those with liver disease (together, "high-risk

individuals"). Exela's L-Cysteine injection product is called Elcys® and was approved by the FDA on April 16, 2019.

20. Elcys® is a parenteral nutrition ("PN") product that delivers essential nutrients intravenously as part of a nutrition regimen for neonates and high-risk individuals. The therapeutically active ingredient in Elcys® is L-cysteine hydrochloride ("cysteine"), which is an amino acid that is necessary for all humans to mitigate oxidative stress on their bodies and promote the proper absorption of essential nutrients. While healthy adults naturally have enough cysteine to meet their needs, neonates and high-risk individuals require daily cysteine infusions as part of a PN regimen.

21. PN products such as Elcys® are critically important to the development and survival of neonates and other high-risk individuals. However, these same PN products can be a major source of aluminum toxicity. Unfortunately, it is impossible to manufacture cysteine drug products that are 100 percent free of impurities, including aluminum.

22. Neonates receiving PN treatments are especially at risk from exposure to trace amounts of aluminum because their kidneys are underdeveloped, which means they cannot expel excess aluminum as efficiently as healthy adults can. The adverse effects of too much neonatal aluminum exposure are well documented: decades of research establish that just a few days of exposure to excess aluminum in neonatal care can lead to lasting toxicity in the brain, skeletal system, liver, and erythropoietic system. Even fleeting exposure to excess amounts of aluminum can pose grave risks to preterm and other neonates.

23. The FDA previously strictly limited the amount of aluminum that could be present in approved PN products, including cysteine. For example, when the FDA was reviewing Elcys®,

it imposed an aluminum concentration limit of 145 micrograms per liter ("mcg/L") in a 5% cysteine solution, *i.e.*, 0.0042 mcg Al/mg cysteine.

24. Exela spent millions of dollars to minimize the amount of aluminum in Elcys® and satisfy this regulatory requirement. The FDA eventually approved Elcys® with a labeled aluminum content amount of no more than 120 mcg/L (0.0035 mcg Al/mg cysteine).

25. In December 2022, however, FDA released an interim "Draft Guidance" proposing to substantially increase the permitted aluminum limits for cysteine. The FDA's December 2022 Draft Guidance suggests that FDA could allow cysteine hydrochloride products intended for PN with aluminum content as high as 2500 mcg/L in a 7.25% cysteine solution, *i.e.*, 0.0500 mcg Al/mg cysteine, which is nearly twelve times the limit that was enforced against Exela.

26. Since then, the FDA has approved a Nivagen Pharmaceuticals, Inc. ANDA (the "Nivagen ANDA") for another cysteine hydrochloride injection product. Similar to Elcys®, the therapeutically active ingredient in the Nivagen ANDA is L-cysteine. However, unlike the low amounts of aluminum permitted in Elcys®, Nivagen has publicly disclosed that the Nivagen ANDA product is approved to contain up to 3000 mcg/L of aluminum in a 7.25% cysteine solution, which is even higher than the already extraordinary 2500 mcg/L limitation proposed in the December 2022 Draft Guidance.

27. Exela submitted three FOIA requests to seek records regarding, *inter alia*, the FDA's proposed decision to increase the aluminum content limits applicable to PN products, external communications with third parties regarding that course of action, and any consideration by the agency regarding the December 2022 Draft Guidance's harmful implications for neonates and high-risk individuals.

A. FOIA Request One

28. Exela submitted FOIA Request One on March 9, 2023, requesting records regarding the development, drafting, and/or publication of the December 2022 Draft Guidance, with the requested date range spanning January 1, 2021 through the date of production. Exs. 1 and 2. This request expressly included, *inter alia*, records within FDA as well as between FDA and any other Federal or State departments or agencies, Congress, and any non-governmental entities or individuals. Ex. 1 at 1-2.

29. FOIA Request One included a request that responsive documents be made available as soon as they are located and reviewed via a rolling production. *Id.* at 4.

30. FOIA Request One also included a request for expedited processing. In making that request, Exela argued that the lack of public information regarding aluminum levels in cysteine drug products could "reasonably be expected to pose an imminent threat to the life or physical safety of" neonates. *Id.* at 2.

31. After submitting FOIA Request One through the online portal, Exela received an automated confirmation of submission of FOIA Request One via email on March 9, 2023, along with a reference number, FDA23090493. Ex. 3.

32. On March 10, 2023, the FDA sent an email to Exela confirming receipt of FOIA Request One and assigning it Control Number 2023-1880. *See* Ex. 4. Attached to the email was a letter dated March 10, 2023, which confirmed that the FDA had received Exela's FOIA request for records and would respond "as soon as possible." Ex. 5.

33. Additionally, in the March 10 letter, the FDA indicated that "[d]ue to an increase in the number of incoming requests" the agency "*may* be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA." Ex.

5 (emphasis added). The FDA then stated that "[t]he actual processing time will depend on the complexity of [Exela's] request and whether sensitive records, voluminous records, extensive search, and/or consultation with other HHS components or other executive branch agencies are involved," but it provided no additional information regarding how long the FDA anticipates the search will take. *Id.*

34. On March 13, 2023, Exela received an email from the FDA regarding its request for expedited processing. Ex. 6. In an attached letter dated March 13, 2023, the FDA denied Exela's request for expedited processing, stating that Exela had not demonstrated a compelling need or urgency. Ex. 7.

35. As of April 7, 2023, at the close of business hours, 20 working days had passed since FDA received Exela's request. *See* 5 U.S.C. § 552(a)(6)(A)(i). The FDA has not informed Exela of any "unusual circumstances."

36. To date, FDA has not (1) made or communicated its determination in response to FOIA Request One, (2) provided any responsive materials, (3) explained that responsive materials have been or will be withheld, (4) communicated any basis for withholding records, or (5) communicated any timeline by which Exela can expect its requests to be processed.

B. FOIA Request Two

37. Exela submitted FOIA Request Two on March 9, 2023, requesting records regarding the Drug Approval Package, Summary Basis of Approval, and any underlying, similar, or related records relating to the submission and review of ANDA 213073, ANDA 214082, and ANDA 209994, with the requested date range spanning January 1, 2021, through the date of production. Exs. 8 and 9. This request expressly included, *inter alia*, all communications within the FDA and by or between the FDA (including any Office, Division, or any other administrative

unit of the Agency, and/or any FDA employees) regarding the aluminum content of the three subject drug products. Ex. 8 at 1-2.

38. FOIA Request Two included a request that responsive documents be made available as soon as they are located and reviewed via a rolling production. *Id.* at 4.

39. FOIA Request Two also included a request for expedited processing. In making that request, Exela argued that the lack of public information regarding aluminum levels in cysteine drug products could "reasonably be expected to pose an imminent threat to the life or physical safety of" neonates. *Id.* at 2-3.

40. After submitting FOIA Request Two through the online portal, Exela received an automated confirmation of submission of FOIA Request Two via email on March 9, 2023, along with a reference number, FDA23090494. Ex. 10.

41. On March 10, 2023, the FDA sent an email to Exela confirming receipt of FOIA Request Two and assigning it Control Number 2023-1881. *See* Ex. 11. Attached to the email was a letter dated March 10, 2023, which confirmed that the FDA had received Exela's FOIA request for records and would respond "as soon as possible." Ex. 12.

42. Additionally, in the March 10 letter, the FDA indicated that "[d]ue to an increase in the number of incoming requests" the agency "*may* be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA." Ex. 12 (emphasis added). The FDA also indicated that "[t]he actual processing time will depend on the complexity of [Exela's] request and whether sensitive records, voluminous records, extensive search, and/or consultation with other HHS components or other executive branch agencies are involved," but it provided no additional information regarding how long the FDA anticipates the search will take. *Id.*

43. On March 13, 2023, Exela received an email from the FDA regarding its request for expedited processing. Ex. 13. In an attached letter dated March 13, 2023, the FDA denied Exela's request for expedited processing, stating that Exela had not demonstrated a compelling need or urgency. Ex. 14.

44. As of April 7, 2023, at the close of business hours, 20 working days had passed since FDA received Exela's request. *See* 5 U.S.C. § 552(a)(6)(A)(i). The FDA has not informed Exela of any "unusual circumstances."

45. To date, FDA has not (1) made or communicated its determination in response to FOIA Request Two, (2) provided any responsive materials, (3) explained that responsive materials have been or will be withheld, (4) communicated any basis for withholding records, or (5) communicated any timeline by which Exela can expect its requests to be processed.

C. FOIA Request Three

46. Exela submitted FOIA Request Three on March 9, 2023, requesting Congressional communications regarding aluminum content in cysteine drug products and other external communications regarding aluminum content in cysteine hydrochloride drug products either generally or regarding specific applications, with the requested date range spanning January 1, 2021 through the date of production. Exs. 15 and 16.

47. FOIA Request Three included a request that responsive documents be made available as soon as they are located and reviewed via a rolling production. Ex. 15 at 4.

48. FOIA Request Three also included a request for expedited processing. In making that request, Exela argued that the lack of public information regarding aluminum levels in cysteine drug products could "reasonably be expected to pose an imminent threat to the life or physical safety of" neonates. *Id.* at 2-3.

49. After submitting FOIA Request Three through the online portal, Exela received an automated confirmation of submission of FOIA Request Three via email on March 9, 2023, along with a reference number, FDA23090497. Ex. 17.

50. On March 10, 2023, the FDA sent an email to Exela confirming receipt of FOIA Request Three and assigning it Control Number 2023-1883. *See* Ex. 18. Attached to the email was a letter dated March 10, 2023, which confirmed that the FDA had received Exela's FOIA request for records and would respond "as soon as possible." Ex. 19.

51. Additionally, in the March 10 letter the FDA indicated that "[d]ue to an increase in the number of incoming requests" the agency "*may* be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA." Ex. 19 (emphasis added). The FDA also indicated that "[t]he actual processing time will depend on the complexity of [Exela's] request and whether sensitive records, voluminous records, extensive search, and/or consultation with other HHS components or other executive branch agencies are involved," but it provided no additional information regarding how long the FDA anticipates the search will take. *Id.*

52. On March 13, 2023, Exela received an email from the FDA regarding its request for expedited processing. Ex. 20. In an attached letter dated March 13, 2023, the FDA denied Exela's request for expedited processing, stating that Exela had not demonstrated a compelling need or urgency. Ex. 21.

53. As of April 7, 2023, at the close of business hours, 20 working days had passed since FDA received Exela's request. *See* 5 U.S.C. § 552(a)(6)(A)(i). The FDA has not informed Exela of any "unusual circumstances."

54. To date, FDA has not (1) made or communicated its determination in response to FOIA Request Three, (2) provided any responsive materials, (3) explained that responsive materials have been or will be withheld, (4) communicated any basis for withholding records, or (5) communicated any timeline by which Exela can expect its requests to be processed.

FIRST CLAIM FOR RELIEF[1]
(Failure to Comply with Statutory Deadlines in Violation of FOIA)

55. Plaintiff repeats, re-alleges, and reincorporates the allegations in the foregoing paragraphs as though fully set forth herein.

56. FOIA requires the FDA to provide a final determination within 20 working days after the receipt of Exela's FOIA request. 5 U.S.C. § 552(a)(6)(A). This 20-day time limit may be extended for a maximum of 10 working days in the event of "unusual circumstances," but written notice must be provided to Exela setting forth the unusual circumstances for such extension and the date on which a determination is expected to be dispatched. *See* 5 U.S.C. § 552(a)(6)(B)(i); *see also* 21 C.F.R. § 20.41(b)(3)(i)(A).

57. If "unusual circumstances" are invoked by an agency through written notice, that agency must also provide the requester with an opportunity to limit the scope of its request so that it may proceed within the statutory time limit or provide the requester an opportunity to arrange with the agency an alternative time frame for processing the request or a modified request. 5 U.S.C. § 552(a)(6)(B)(ii); *see also* 21 C.F.R. § 20.41(b)(3)(i)(B).

58. More than 20 working days have passed since Exela's three FOIA requests were received and logged by the FDA on March 10, 2023. *See* Exs. 5, 12, and 19.

[1] Each claim for relief brought by Exela in this complaint applies to all three FOIA requests detailed above.

59. To date, the FDA has not provided a final determination in response to Exela's FOIA requests, nor has it communicated when Exela can expect its requests to be processed.

60. The FDA has not provided written notice to Exela that it is invoking "unusual circumstances" under the statute. In its March 10, 2023, letter, the FDA only stated that it "may" take longer than 20 working days or longer than the additional 10 days allotted for "unusual circumstances." *See* Exs. 5, 12 and 19. Furthermore, by indicating only that the requests cannot be accommodated because of an increase in the number of requests the FDA has received, the FDA failed to satisfy the statutory requirement of providing written notice to Exela of setting forth the "unusual circumstances" for such extension and the date on which a determination is expected to be dispatched, *see* 5 U.S.C. § 552(a)(6)(B)(i); *see also* Exs. 5, 12, and 19. An "increase" in the number of FOIA requests received by the FDA is not a statutorily authorized basis for invoking "unusual circumstances" under FOIA. *See* 5 U.S.C. § 552 (a)(6)(B)(iii); *see also* 21 C.F.R. § 20.41(b)(3)(ii).

61. The FDA also has not given Exela an opportunity to limit the scope of its requests so they may be processed within the statutory time frame, which FOIA requires if "unusual circumstances" are to be invoked. *See* 5 U.S.C. § 552(a)(6)(B)(ii); *see also* 21 C.F.R. § 20.41(b)(3)(i)(B). Nor has the FDA provided Exela an opportunity to arrange for an alternative time frame for processing the request or a modified request that would be acceptable to both parties. *See* 5 U.S.C. § 552(a)(6)(B)(ii); *see also* 21 C.F.R. § 20.41(b)(3)(i)(B).

62. The FDA has failed to make a timely determination in response to Exela's FOIA requests, in violation of FOIA. *See* 5 U.S.C. § 552(a)(6).

63. All administrative remedies required by FOIA have been constructively exhausted. *See* 5 U.S.C. § 552(a)(6)(C)(i).

SECOND CLAIM FOR RELIEF
(Unlawful Withholding of Agency Records in Violation of FOIA)

64. The allegations in the foregoing paragraphs are expressly incorporated herein as if restated in full.

65. FOIA requires the FDA to process records requests and promptly provide the requested records or the reasonably segregable portion of records not subject to a FOIA exemption. 5 U.S.C. § 552(a)(3)(A).

66. To date, the FDA has neither provided nor made available any responsive documents in response to Exela's FOIA requests, nor has the FDA claimed that any responsive records are exempt from disclosure.

67. Therefore, the FDA's failure to promptly produce requested records or claim applicable exemptions violates FOIA. 5 U.S.C. § 552(a)(3)(A).

THIRD CLAIM FOR RELIEF
(Declaratory Judgment)

68. The allegations in the foregoing paragraphs are expressly incorporated herein as if restated in full.

69. For the same reasons described in each of the previous counts, Exela is entitled to a declaratory judgment that the FDA has been and is violating the law.

PRAYER FOR RELIEF

Plaintiff respectfully requests that the Court:

A. Declare that the FDA failed to make and communicate a timely determination regarding each of Exela's three requests, in violation of FOIA, 5 U.S.C. §§ 552(a)(6)(A)(i), (a)(6)(E)(iii);

B. Declare that the FDA failed to promptly provide records responsive to each of Exela's three requests, in violation of FOIA, 5 U.S.C. § 552(a)(3);

C. Order the FDA to immediately conduct a reasonable search for all responsive records and demonstrate that it employed search methods reasonably calculated to uncover all records responsive to the requests as required by FOIA, 5 U.S.C. § 552(a)(3)(C);

D. Order the FDA to immediately provide a determination on Exela's requests as required by FOIA, 5 U.S.C. § 552(a)(6)(A)(i), and produce a *Vaughn* index of any responsive records withheld under claim of exemption, *see Judicial Watch, Inc. v. FDA*, 449 F.3d 141, 145–46 (D.C. Cir. 2006);

E. Order the FDA to promptly make available to Exela all responsive, non-exempt records, as required by FOIA, 5 U.S.C. § 552(a)(3);

F. Maintain jurisdiction over this action to ensure that the FDA produces all non-exempt responsive records to Exela, and that any non-exempt portions of responsive records are not improperly withheld;

G. Award reasonable attorneys' fees and allowable costs, including under 5 U.S.C. § 552(a)(4)(E); and

H. Grant Exela such other and further relief to which it is justly entitled at law and in equity.

Dated: April 10, 2023

Respectfully submitted,

/s/ Jonathan P. Lienhard
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