

**EXHIBIT A:
FOIA Request**

**Complaint for Injunctive Relief,
Reed Smith LLP v. Food & Drug Administration,
Civil Action No. 20-2786**



Driving progress
through partnership

Rachael G. Pontikes

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July 24, 2020

Via Online Access Portal

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 Request

To Whom It May Concern:

We are submitting the following Freedom of Information Act (“FOIA”) request to the U.S. Food & Drug Administration (“FDA”).

A. Requestor's name, address, and telephone number.

Rachael Pontikes
10 South Wacker Drive
40th Floor
Chicago, IL 60606
(312) 207-2857

B. A description of the records being sought. The records should be identified as specifically as possible. A request for specific records that are releasable to the public can be processed much more quickly than a request for "all information" on a particular subject. Also fees for a more specific and limited request will generally be less.

I request the following records:

- All communications* between FDA (including, but not limited to, FDA’s Center for Drug Evaluation and Research (“CDER”)) and the National Academies of Sciences, Engineering, and Medicine (including, but not limited to, Leigh Jackson), from January 1, 2016, to the present regarding the following subjects:

* For purposes of this FOIA request, the term “communications” includes, but is not limited to, e-mail messages, letters, memoranda, and calendar invitations and notations.

Food and Drug Administration
July 24, 2020
Page 2

ReedSmith

- Bioidentical hormones;
 - Compounded bioidentical hormone therapy (otherwise known as “cBHT” or “cBHRT”);
 - Difficult to compound;
 - Clinical utility ;
 - Pharmacy Compounding Advisory Committee (otherwise known as “PCAC”);
 - Jane Axelrad; or
 - Axelrad Solutions LLC.
- All communications between FDA (including, but not limited to, FDA’s CDER) and Jane Axelrad from May 1, 2016, to the present regarding the following subjects:
 - National Academies of Sciences, Engineering, and Medicine (otherwise known as “NASEM”);
 - Bioidentical hormones;
 - Compounded bioidentical hormone therapy (otherwise known as “cBHT” or “cBHRT”);
 - Difficult to compound;
 - Clinical utility; or
 - Pharmacy Compounding Advisory Committee (otherwise known as “PCAC”).
- All communications between FDA (including, but not limited to, FDA’s CDER) and Axelrad Solutions LLC from December 6, 2016, to the present regarding the following subjects:
 - National Academies of Sciences, Engineering, and Medicine (otherwise known as “NASEM”);
 - Bioidentical hormones;
 - Compounded bioidentical hormone therapy (otherwise known as “cBHT” or “cBHRT”);
 - Difficult to compound;
 - Clinical utility; or
 - Pharmacy Compounding Advisory Committee (otherwise known as “PCAC”).
- All communications between FDA (including, but not limited to, FDA’s CDER) and the Pharmacy Compounding Advisory Committee, from November 27, 2013, to the present regarding the following subjects:
 - Bioidentical hormones;
 - Compounded bioidentical hormone therapy (otherwise known as “cBHT” or “cBHRT”);
 - Difficult to compound;
 - Clinical utility;
 - National Academies of Sciences, Engineering, and Medicine (otherwise known as “NASEM”);
 - Jane Axelrad; or
 - Axelrad Solutions LLC.

Food and Drug Administration
July 24, 2020
Page 3

ReedSmith

C. A statement concerning willingness to pay fees, including any limitations.

I will pay all fees associated with this request. If the agency estimates that those fees will exceed \$1,000.00, please contact me before proceeding further.

Very truly yours,

Rachael G. Pontikes

Rachael G. Pontikes
For Reed Smith LLP

RGP:rl