UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

ThermoLife International, LLC

v.

United States Department of Health and Human Services

Case No.

COMPLAINT

Exhibit 1: May 29, 2015 FOIA Request

KERCSMAR
& FELTUS PLLC
www.businesslawaz.com

7150 East Camelback Road, Suite 285
Scottsdale, AZ 85251
(480) 421-1001 • Fax (480) 421-1002

Gregory B. Collins
gbc@kflawaz.com

May 29, 2015

VIA EMAIL and FIRST-CLASS MAIL

Lauren DiPaola
Office of Policy and Risk Management
Food and Drug Administration
12420 Parklawn Drive
Element Bldg., Room 4042
Rockville, Maryland 20857
Lauren.DiPaola@fda.hhs.gov

Re: Freedom of Information Act Request

Dear Ms. DiPaola,

This public records request is submitted by my office, on behalf of a client of the Kercsmar & Feltus, PLLC. My contact information appears above. I have addressed this letter to your attention because you previously assisted my office in obtaining documents in response to a public records request that you responded to on May 1, 2013.

On September 15, 2014, the United States House of Representatives passed "The De signer Anabolic Steroid Control Act of 2014." The bill amended "The Controlled Substances Act" to more effectively regulate anabolic steroids and the bill is now codified as 21 U.S.C. §§ 355 & 811, 18 U.S.C. §§ 21, 811, & 825, among other code sections.

The bill was original proposed by Representative Joseph Pitts on May 29, 2014. As introduced, the bill listed 27 compounds that were specifically identified as "Designer Anabolic Steroids." The second and third compounds on the as-introduced bill, were: (i) Androst-4-ene-3,6,17-trione and (ii) Androsta-1,4,6-triene-3,17-dione. Although Androst-4-ene-3,6,17-trione and Androsta-1,4,6-triene-3,17-dione were listed in the introduced bill, the enacted version of the bill omitted these two compounds. We have inquired regarding the omission of these two compounds from the final bill. In response to our inquiries, we were informed that these compounds were removed from the bill as a result of comments and input provided by your office, the FDA.

We request the following public information:

1. Any and all written communications (including, but not limited to, email communications) that any FDA employee, representative, agent, or attorney had with anyone related to "The Designer Anabolic Steroid Control Act of 2014" between May 29, 2014 and September 15, 2014.

2. Any and all written communications (including, but not limited to, email communications) that any FDA employee, representative, agent or attorney had with anyone related to Androst-4-ene-3,6,17-trione between May 29, 2014 and September 15, 2014.

3. Any and all written communications (including, but not limited to, email communications) that any FDA employee, representative, agent or attorney had with anyone related to Androsta-1,4,6-triene-3,17-dione between May 29, 2014 and September 15, 2014.

We are willing to pay fees and costs incurred gathering and providing the above documents of up to $500.00. If you anticipate the fees and costs will exceed $500.00, please contact me so that we can determine how to proceed.

I look forward to hearing from you and we would appreciate prompt production of these documents.

Best regards,

KERCSMAR & FELTUS PLLC

Gregory B. Collins

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

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COMPLAINT

Exhibit 2: June 4, 2015 Confirmation of Receiving FOIA Request

KERCSMAR
& FELTUS PLLC
www.businesslawaz.com

7150 EAST CAMELBACK ROAD, SUITE 285
SCOTTSDALE, AZ 85251
(480) 421-1001 • FAX (480) 421-1002

JUN 04 2015

Gregory B. Collins
gbc@kflawaz.com

May 29, 2015

VIA EMAIL and FIRST-CLASS MAIL

Lauren DiPaola
Office of Policy and Risk Management
Food and Drug Administration
12420 Parklawn Drive
Element Bldg., Room 4042
Rockville, Maryland 20857
Lauren.DiPaola@fda.hhs.gov

Commercial ✓
Nonprofit/Media ___
Other ___

2015-4445

Re: Freedom of Information Act Request

Dear Ms. DiPaola,

This public records request is submitted by my office, on behalf of a client of the Kercsmar & Feltus, PLLC. My contact information appears above. I have addressed this letter to your attention because you previously assisted my office in obtaining documents in response to a public records request that you responded to on May 1, 2013.

On September 15, 2014, the United States House of Representatives passed "The De signer Anabolic Steroid Control Act of 2014." The bill amended "The Controlled Substances Act" to more effectively regulate anabolic steroids and the bill is now codified as 21 U.S.C. §§ 355 & 811, 18 U.S.C. §§ 21, 811, & 825, among other code sections.

The bill was original proposed by Representative Joseph Pitts on May 29, 2014. As introduced, the bill listed 27 compounds that were specifically identified as "Designer Anabolic Steroids." The second and third compounds on the as-introduced bill, were: (i) Androst-4-ene-3,6,17-trione and (ii) Androsta-1,4,6-triene-3,17-dione. Although Androst-4-ene-3,6,17-trione and Androsta-1,4,6-triene-3,17-dione were listed in the introduced bill, the enacted version of the bill omitted these two compounds. We have inquired regarding the omission of these two compounds from the final bill. In response to our inquiries, we were informed that these compounds were removed from the bill as a result of comments and input provided by your office, the FDA.

Of C
OL
CDER

We request the following public information:

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3. Any and all written communications (including, but not limited to, email communications) that any FDA employee, representative, agent or attorney had with anyone related to Androsta-1,4,6-triene-3,17-dione between May 29, 2014 and September 15, 2014.

We are willing to pay fees and costs incurred gathering and providing the above documents of up to $500.00. If you anticipate the fees and costs will exceed $500.00, please contact me so that we can determine how to proceed.

I look forward to hearing from you and we would appreciate prompt production of these documents.

Best regards,

KERCSMAR & FELTUS PLLC

Gregory B. Collins

Recipient Information

To: FOIA Request
Company: FDA
Fax #: 3018279267

Sender Information

From: Greg Collins
Company: Kercsmar & Feltus PLLC
Email address: bjb@kflawaz.com (from 67.51.195.178)
Phone #: 4804211001
Sent on: Wednesday, June 3 2015 at 1:22 PM EDT

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

ThermoLife International, LLC

v.

United States Department of Health and Human Services

Case No.

COMPLAINT

Exhibit 3: December 11, 2015 Letter from Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

December 11, 2015

In Reply Refer To: 2015-4445

Kercsmar & Feltus PLLC
Gregory B. Collins
7150 East Camelback Rd., Suite 285
Scottsdale, AZ 85251

Dear Requester:

This is in response to your Freedom of Information Act request (attached) regarding DESIGNER ANABOLIC STERIOID CONTROL ACT OF 2014 - COMM, EMAILS. Your request has been assigned tracking number FOIA 2015-4445.

After a diligent search of our files, the Office of the Executive Secretariat (OES) was unable to locate any records responsive to your request. Your request is still being handled by Center for Drug Evaluation and Research (CDER) and Office of Legislation (OL).

If you wish to appeal this determination, please submit your appeal within 30 days to:

Director, News Division
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
Parklawn Building, Room 19-01
5600 Fishers Lane
Rockville, MD 20857

Please mark your envelope FDA FOIA Appeal and please include your control number FOIA 2015-4445.

Sincerely,

Sarah B. Kotler, JD
Director, Division of Freedom of Information
U.S. Food & Drug Administration

KERCSMAR
& FELTUS PLLC
www.businesslawaz.com

7150 EAST CAMELBACK ROAD, SUITE 285
SCOTTSDALE, AZ 85251
(480) 421-1001 • FAX (480) 421-1002

JUN 04 2015

Gregory B. Collins
gbc@kflawaz.com

May 29, 2015

VIA EMAIL and FIRST-CLASS MAIL

Commercial ✓
Nonprofit/Media _
Other _____

2015-4445

Lauren DiPaola
Office of Policy and Risk Management
Food and Drug Administration
12420 Parklawn Drive
Element Bldg., Room 4042
Rockville, Maryland 20857
Lauren.DiPaola@fda.hhs.gov

Re: Freedom of Information Act Request

Dear Ms. DiPaola,

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OFC
OL
CDER

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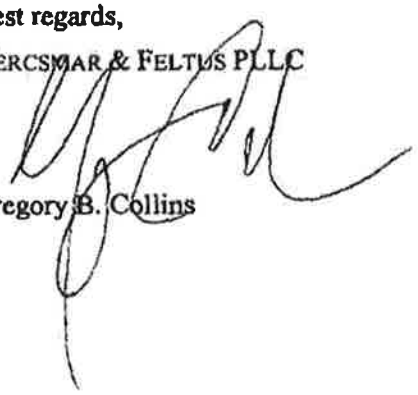
3. Any and all written communications (including, but not limited to, email communications) that any FDA employee, representative, agent or attorney had with anyone related to Androsta-1,4,6-triene-3,17-dione between May 29, 2014 and September 15, 2014.

We are willing to pay fees and costs incurred gathering and providing the above documents of up to $500.00. If you anticipate the fees and costs will exceed $500.00, please contact me so that we can determine how to proceed.

I look forward to hearing from you and we would appreciate prompt production of these documents.

Best regards,

KERCSMAR & FELTUS PLLC



Gregory B. Collins

Recipient Information

To: FOIA Request
Company: FDA
Fax #: 3018279267

Sender Information

From: Greg Collins
Company: Kercsmar & Feltus PLLC
Email address: bjb@kflawaz.com (from 67.51.195.178)
Phone #: 4804211001
Sent on: Wednesday, June 3 2015 at 1:22 PM EDT

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

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United States Department of Health and Human Services

Case No.

COMPLAINT

Exhibit 4: April 7, 2016 and subsequent emails between S. Kotler, G. Collins and J. Wagner

Julia Wagner

From: Kotler, Sarah <Sarah.Kotler@fda.hhs.gov>
Sent: Tuesday, June 28, 2016 3:06 PM
To: Julia Wagner
Cc: Gregory Collins; Russ, Wilson
Subject: RE: FDA FOIA Request Nos. 2015-4445 and 2016-4047

Dear Ms. Wagner,

In response to your email below, I have asked the Office of Legislation to contact you regarding the status of your request 2016-4047, and I have asked the Center for Drugs to contact you regarding 2015-4445.

Sincerely,

Sarah B. Kotler, JD
Director, Division of Freedom of Information
U.S. Food & Drug Administration
5630 Fishers Lane, Room 1033
Rockville, MD 20857
(301)796-8976

From: Julia Wagner [mailto:jaw@kflawaz.com]
Sent: Tuesday, June 28, 2016 5:25 PM
To: Kotler, Sarah
Cc: Gregory Collins
Subject: FDA FOIA Request Nos. 2015-4445 and 2016-4047

Ms. Kotler,

I am following up on the status of Request No. 2016-4047. Please advise if there is someone else I need to contact to get a response. We have been waiting for nearly two months for responsive documents.

In addition, we are still awaiting documents responsive to Request No. 2015-4445. While we have received some documents, you indicated there are other departments looking for responsive documents (see email below). That request has been pending for over a year.

HHS/FDA is well beyond the statutorily mandated FOIA response time. Accordingly, we have exhausted our administrative remedies. Please provide documents by July 12, 2016.

If we fail to receive documents by July 12, 2016, we will file a lawsuit against HHS/FDA to compel you to provide responsive documents. We will also seek our fees due to HHS/FDA bad faith in failing to respond in a timely manner. Your attention is appreciated.

Thank you.

Julia A. Wagner
Kercsmar & Feltus PLLC
7150 E. Camelback Road, Suite 285
Scottsdale, Arizona 85251
480.990.6223 (direct)
480.421.1001 (main)
480.421.1002 (facsimile)
jaw@kflawaz.com
www.kflawaz.com
www.businesslawaz.com

From: Kotler, Sarah [mailto:Sarah.Kotler@fda.hhs.gov]
Sent: Thursday, April 07, 2016 8:50 AM
To: Gregory Collins
Cc: Russ, Wilson
Subject: FDA FOIA Response 2015-4445

Dear Mr. Collins,

Please find attached a partial response to your request. These are records from the FDA's Office of Legislation. Your request remains open and pending with the FDA's Center for Drug Evaluation and Research. Please note that information has been withheld under Exemption 6 of the FOIA on two pages of this response, as indicated on the pages. You will receive appeal rights with your final response from the agency.

Sincerely,

Sarah B. Kotler, JD
Director, Division of Freedom of Information
U.S. Food & Drug Administration
5630 Fishers Lane, Room 1033
Rockville, MD 20857
(301)796-8976

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

ThermoLife International, LLC

v.

United States Department of Health and Human Services

Case No.

COMPLAINT

Exhibit 5: December 20, 2016 email between J. Wagner to S. Kotler

Julia Wagner

From: Kotler, Sarah <Sarah.Kotler@fda.hhs.gov>
Sent: Tuesday, December 20, 2016 1:26 PM
To: Julia Wagner
Cc: Gregory Collins; Russ, Wilson
Subject: RE: FDA FOIA Request Nos. 2015-4445 and 2016-4047

Hi, Ms. Wagner. Your request is assigned to Gary Jackson at CDER. I asking him to contact you.

Thanks,

Sarah B. Kotler, J.D.
Director
Office of the Executive Secretariat
Division of Freedom of Information
U.S. Food and Drug Administration
Tel: 301-796-8976
Sarah.Kotler@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

From: Julia Wagner [mailto:jaw@kflawaz.com]
Sent: Tuesday, December 20, 2016 3:21 PM
To: Kotler, Sarah
Cc: Gregory Collins; Russ, Wilson
Subject: RE: FDA FOIA Request Nos. 2015-4445 and 2016-4047

Ms. Kotler,

In follow up to your email below, I have not heard from the Center for Drugs regarding request 2015-4445. Who do I need to contact to get a response? Thanks.

Julia A. Wagner
Kercsmar & Feltus PLLC
7150 E. Camelback Road, Suite 285
Scottsdale, Arizona 85251
480.990.6223 (direct)
480.421.1001 (main)
480.421.1002 (facsimile)
jaw@kflawaz.com
www.kflawaz.com
www.businesslawaz.com

KERCSMAR & FELTUS PLLC
www.businesslawaz.com

From: Kotler, Sarah [mailto:Sarah.Kotler@fda.hhs.gov]
Sent: Tuesday, June 28, 2016 3:06 PM
To: Julia Wagner
Cc: Gregory Collins; Russ, Wilson
Subject: RE: FDA FOIA Request Nos. 2015-4445 and 2016-4047

Dear Ms. Wagner,

In response to your email below, I have asked the Office of Legislation to contact you regarding the status of your request 2016-4047, and I have asked the Center for Drugs to contact you regarding 2015-4445.

Sincerely,

Sarah B. Kotler, JD
Director, Division of Freedom of Information
U.S. Food & Drug Administration
5630 Fishers Lane, Room 1033
Rockville, MD 20857
(301)796-8976

From: Julia Wagner [mailto:jaw@kflawaz.com]
Sent: Tuesday, June 28, 2016 5:25 PM
To: Kotler, Sarah
Cc: Gregory Collins
Subject: FDA FOIA Request Nos. 2015-4445 and 2016-4047

Ms. Kotler,

I am following up on the status of Request No. 2016-4047. Please advise if there is someone else I need to contact to get a response. We have been waiting for nearly two months for responsive documents.

In addition, we are still awaiting documents responsive to Request No. 2015-4445. While we have received some documents, you indicated there are other departments looking for responsive documents (see email below). That request has been pending for over a year.

HHS/FDA is well beyond the statutorily mandated FOIA response time. Accordingly, we have exhausted our administrative remedies. Please provide documents by July 12, 2016.

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Thank you.

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480.990.6223 (direct)
480.421.1001 (main)
480.421.1002 (facsimile)
jaw@kflawaz.com
www.kflawaz.com
www.businesslawaz.com

From: Kotler, Sarah [mailto:Sarah.Kotler@fda.hhs.gov]
Sent: Thursday, April 07, 2016 8:50 AM
To: Gregory Collins
Cc: Russ, Wilson
Subject: FDA FOIA Response 2015-4445

Dear Mr. Collins,

Please find attached a partial response to your request. These are records from the FDA's Office of Legislation. Your request remains open and pending with the FDA's Center for Drug Evaluation and Research. Please note that information has been withheld under Exemption 6 of the FOIA on two pages of this response, as indicated on the pages. You will receive appeal rights with your final response from the agency.

Sincerely,

Sarah B. Kotler, JD
Director, Division of Freedom of Information
U.S. Food & Drug Administration
5630 Fishers Lane, Room 1033
Rockville, MD 20857
(301)796-8976

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

ThermoLife International, LLC

v.

United States Department of Health and Human Services

Case No.

COMPLAINT

Exhibit 6: December 21, 2016 email between G. Jackson and J. Wagner

Julia Wagner

From: Jackson, Gary (CDER) <Gary.Jackson1@fda.hhs.gov>
Sent: Wednesday, December 21, 2016 8:22 AM
To: Julia Wagner
Cc: Landy, Eli
Subject: RE: FOIA 2014-4445

Ms. Wagner,

The correct case number is 2015-4445. Your correct place in the queue is 272. My apologies for any confusion.

Gary

From: Jackson, Gary (CDER)
Sent: Wednesday, December 21, 2016 10:17 AM
To: 'jaw@kflawaz.com'
Cc: Landy, Eli
Subject: FOIA 2014-4445

Good morning Ms. Wagner,

Regarding your FOIA processing status inquiry to the Center for Drug Evaluation and Research (CDER), please be advised that your request is currently number Two Hundred and Seventy Two (272) out of approximately Six Hundred and Twenty Five (625) requests. The FDA CDER processes FOI requests in a two track system. That system operates on a first in first out basis. Your request has been assigned to the complex queue and will be processed in turn.

Regards,
Gary W. Jackson
Consumer Safety Officer

Division of Information Disclosure Policy
Center for Drug Evaluation and Research

****
****

From: Julia Wagner [mailto:jaw@kflawaz.com]
Sent: Tuesday, December 20, 2016 3:21 PM
To: Kotler, Sarah
Cc: Gregory Collins; Russ, Wilson
Subject: RE: FDA FOIA Request Nos. 2015-4445 and 2016-4047

Ms. Kotler,

In follow up to your email below, I have not heard from the Center for Drugs regarding request 2015-4445. Who do I need to contact to get a response? Thanks.

Julia A. Wagner
Kercsmar & Feltus PLLC
7150 E. Camelback Road, Suite 285
Scottsdale, Arizona 85251

480.990.6223 (direct)
480.421.1001 (main)
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www.kflawaz.com
www.businesslawaz.com

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

ThermoLife International, LLC

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Case No.

COMPLAINT

Exhibit 7: October 23, 2107 Letter to S. Kotler from J. Wagner

KERCSMAR & FELTUS PLLC
www.businesslawaz.com

7150 EAST CAMELBACK ROAD, SUITE 285
SCOTTSDALE, AZ 85251
(480) 421-1001 • FAX (480) 421-1002

Julia A. Wagner
jaw@kflawaz.com

October 23, 2017

VIA EMAIL and FIRST-CLASS MAIL

Sarah Kotler
Director, Division of Freedom of Information
U.S. Food & Drug Administration
12420 Parklawn Drive
5630 Fishers Lane, Room 1033
Rockville, Maryland 20857
Sarah.Kotler@fda.hhs.gov

Re: *Freedom of Information Act Request*; Request No. 2015-4445

Dear Ms. Kotler:

Our office submitted a public records request on behalf of our client, Thermolife International, Inc., on May 29, 2015, request number 2015-4445. Your office provided a partial response on April 7, 2016. That same day, you indicated that the request remained open and pending with the FDA's Center for Drug Evaluation and Research. It has been over a year and we have heard nothing. Please provide a response no later than November 6, 2017.

Should your agency fail to comply, Thermolife International, Inc. has authorized this firm to file a complaint on its behalf to compel production of the records in response to the FOIA request. The nearly two and a half year delay warrants a finding of bad faith, and we will seek our fees and costs in bringing the lawsuit.

I look forward to hearing from you.

Best regards,

KERCSMAR & FELTUS PLLC

Julia Wagner

Julia A. Wagner

JAW/mlg

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

ThermoLife International, LLC

v.

United States Department of Health and Human Services

Case No.

COMPLAINT

Exhibit 8: October 24, 2107 email from G. Jackson to J. Wagner

Julia Wagner

From: Jackson, Gary (CDER) <Gary.Jackson1@fda.hhs.gov>
Sent: Tuesday, October 24, 2017 7:42 AM
To: Julia Wagner
Subject: FOIA 2015-4445

Good morning Ms. Wagner,

Regarding your FOIA processing status inquiry to the Center for Drug Evaluation and Research (CDER), please be advised that your request is approximately number One Hundred Sixty-Eight in the queue. The FDA CDER processes FOI requests in a two-track system. That system operates on a
first in first out basis. Your request has been assigned to the complex queue and will be processed in turn.

Regards,
Gary W. Jackson
Consumer Safety Officer

Division of Information Disclosure Policy
Center for Drug Evaluation and Research