

ORIGINAL



UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

)
In the Matter of)
)
)
POM WONDERFUL LLC and,)
ROLL GLOBAL LLC,)
as successor in interest to)
Roll International Corporation,)
companies, and)
)
STEWART A. RESNICK,)
LYNDA RAE RESNICK, and)
MATTHEW TUPPER, individually and)
as officers of the companies.)
_____)

Docket No. 9344

PUBLIC DOCUMENT

**COMPLAINT COUNSEL’S MOTION REQUESTING
IN CAMERA TREATMENT OF CERTAIN DOCUMENTS
PRODUCED BY THE FOOD AND DRUG ADMINISTRATION**

Complaint Counsel moves, pursuant to Rule 3.45(b), for an order allowing *in camera* treatment of certain documents produced by the Food and Drug Administration (“FDA”) to the Federal Trade Commission (“FTC” or “Commission”). As explained more fully below, the FDA provided these documents to the FTC [REDACTED] [REDACTED] and subject to a federal regulation, 21 C.F.R. § 20.85, that prohibits public disclosure of the materials by the FTC without the FDA’s written permission. Because public release of these documents at the administrative trial would likely result in a “clearly defined, serious injury,” 16 C.F.R. § 3.45(b), as described below, the documents should be granted *in camera* treatment.¹

¹ On April 20, 2011, Complaint Counsel Mary Johnson and Serena Viswanathan contacted Respondents’ Counsel John Graubert regarding this motion. Respondents’ Counsel stated that while Respondents had no objection to Complaint Counsel filing this motion, they were taking no position on any of the substantive statements therein.

[REDACTED]

As set forth in the accompanying declaration from Nancy B. Sager of the FDA (“Sager Dec.”), [REDACTED]

Under Rule 3.45(b) of the Commission’s Rules of Practice, the Court may grant *in camera* treatment to material after finding that “its public disclosure will likely result in a clearly defined, serious injury to the person, partnership, or corporation requesting *in camera* treatment.” 16 C.F.R. § 3.45(b). In her declaration, Ms. Sager states that [REDACTED]

[REDACTED]

² The documents are FTC-0007436-7797; FTC-0013759-13802; and FTC-0013804-15288. [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED] and Complaint Counsel notes that such a result would harm its ability to enforce the law. Thus, Complaint Counsel requests that the Court grant *in camera* treatment for the documents identified in the Sager Declaration. [REDACTED]

Respectfully submitted,

Date: April 20, 2011

/s/ Serena Viswanathan
Mary L. Johnson (202) 326-3115
Serena Viswanathan (202) 326-3244
Federal Trade Commission
Bureau of Consumer Protection
600 New Jersey Avenue, NW, Room NJ-3212
Washington, DC 20580

**UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION**

_____)	
In the Matter of)	
)	
POM WONDERFUL LLC and,)	
ROLL GLOBAL LLC,)	
as successor in interest to)	
Roll International Corporation,)	
companies, and)	Docket No. 9344
)	
STEWART A. RESNICK,)	
LYNDA RAE RESNICK, and)	
MATTHEW TUPPER, individually and)	
as officers of the companies.)	
_____)	

[PROPOSED] ORDER GRANTING *IN CAMERA* TREATMENT

On April 20, 2011, Complaint Counsel filed a Motion Requesting In Camera Treatment of Certain Documents Produced by the Food and Drug Administration (“Complaint Counsel’s Motion”). Upon full consideration of the motion and the accompanying exhibits and declaration, Complaint Counsel’s motion is GRANTED. It is hereby ORDERED that *in camera* treatment will be extended to the documents identified in Complaint Counsel’s Motion until such time as the Food and Drug Administration provides written permission for further release of any nonpublic information contained therein.

ORDERED:

D. Michael Chappell
Chief Administrative Law Judge

Dated:

CERTIFICATE OF SERVICE

I certify that on April 20, 2011 I caused the filing and serving of *Complaint Counsel's Motion Requesting In Camera Treatment of Certain Documents Produced by the Food and Drug Administration* upon the following as set forth below:

One electronic copy of the redacted, public document via the FTC E-Filing System, and the paper original and paper copies of the full confidential document via hand delivery to:

Donald S. Clark, Secretary
Federal Trade Commission
600 Pennsylvania Ave., N.W., Room H-159
Washington, DC 20580

One paper copy via hand delivery and one electronic copy via email to:

The Honorable D. Michael Chappell
Administrative Law Judge
600 Pennsylvania Ave., N.W., Room H-110
Washington, DC 20580
Email: oalj@ftc.gov

One electronic copy via email to:

John D. Graubert, Esq.
Skye L. Perryman, Esq.
Covington & Burling LLP
1201 Pennsylvania Ave., NW
Washington DC 20004-2401
Email: jgraubert@cov.com; sperryman@cov.com

Kristina Diaz, Esq.
Roll Law Group
Email: kdiaz@roll.com
Attorneys for Respondents

Bertram Fields, Esq.
Greenberg Glusker
Email: bfields@greenbergglusker.com
Attorneys for Respondents Stewart Resnick and Lynda Resnick

/s/ Serena Viswanathan
Serena Viswanathan
Complaint Counsel

**UNITED STATES OF AMERICA
THE FEDERAL TRADE COMMISSION**

In the Matter of)
)
POM WONDERFUL LLC and)
ROLL GLOBAL LLC,)
as successor in interest to)
Roll International Corporation,)
companies and) Docket No. 9344
)
STEWART A. RESNICK,)
LYNDA RAE RESNICK, and)
MATTHEW TUPPER, individually and)
as officers of the companies.)
_____)

DECLARATION OF NANCY B. SAGER

I, Nancy B. Sager, declare as follows:


1. The statements made in this declaration are based upon my personal knowledge.
2. I submit this declaration in support of the Federal Trade Commission's ("FTC's")

Motion for In Camera Review of documents FDA provided to FTC under 21 C.F.R. § 20.85. [REDACTED]

[REDACTED]

3. I am the Director of the Division of Information Disclosure Policy ("DIDP"), Center for Drug Evaluation and Research ("CDER"), United States Food and Drug Administration ("FDA"), in Silver Spring, Maryland. I have supervisory authority over DIDP, which processes and responds to requests for CDER documents made by the U.S. Congress, foreign, state, and local governments, and other federal agencies, and by third-party subpoenas and court orders and by the public in response to requests made under the Freedom of Information Act (5 U.S.C. § 552).

4. At my direction, DIDP personnel assisted with producing documents for the above-captioned matter, which now comprise 27 of FTC's proposed exhibits and bear BATES

numbers: FTC-0007436-0007797; FTC-0013759-0013802; and, FTC-0013804-0015288. 







7. FDA's regulation, 21 C.F.R. § 20.85, provides that, with limited exception, FDA records that are otherwise exempt from public disclosure may be disclosed to other Federal Government department and agencies, such as FTC. The regulation further provides that any disclosure under 21 C.F.R. § 20.85 shall be pursuant to a written agreement, and that the record(s) will not be further disclosed without FDA's written permission.

8. In 1971, FTC and FDA executed a Memorandum of Understanding Concerning Exchange of Information, which generally sets forth the framework for exchange of information between the two agencies. *See* FDA Memorandum of Understanding 225-71-8003, *available at*

[http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/
DomesticMOUs/ucm115791.htm.](http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm115791.htm) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



Accordingly, the Government requests that such information not be made public, and be subject to *in camera* review only.

Pursuant to 28 U.S.C. § 1746, I declare under the penalty of perjury that the foregoing is true and correct.

NANCY B. SAGER
Director, Division of Information
Disclosure Policy
Center for Drug Evaluation and Research
Food and Drug Administration
U.S. Dept. of Health and Human Services

Executed on April 20, 2011, in Silver Spring, Maryland.

EXHIBIT A



UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Division of Advertising Practices

February 1, 2010

VIA EMAIL

Ms. Jennifer Thomas
Division of Enforcement (HFS-605)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
College Park, MD 20740

Ms. Christine Bechtel
Office of Executive Programs (HFD-006)
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
College Park, MD 20740

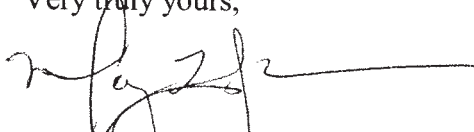
Dear Ms. Thomas and Ms. Bechtel:

Ms. Jennifer Thomas and Ms. Christine Bechtel
February 1, 2010
Page 2



If you have any questions, please contact me at the Federal Trade Commission,
600 Pennsylvania Ave. NW, Rm. NJ-3212, Washington, DC 20580; Phone: 202-326-3115;
Fax: 202-326-3259; Email: mjohnson1@ftc.gov.

Very truly yours,



Mary L. Johnson

A handwritten signature in black ink, appearing to read 'Mary L. Johnson', is written over the typed name. The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Attachment



Food and Drug Administration
Rockville MD 20857

May 8, 2008

Jeffrey Schmidt
Director
Bureau of Competition
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Lydia B. Parnes
Director
Bureau of Consumer Protection
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Dear Mr. Schmidt and Ms. Parnes:





Sincerely,

A handwritten signature in black ink, appearing to read "D. Elder", is written over the typed name.

David Elder
Director
Office of Enforcement
Office of Regulatory Affairs
U.S. Food and Drug Administration

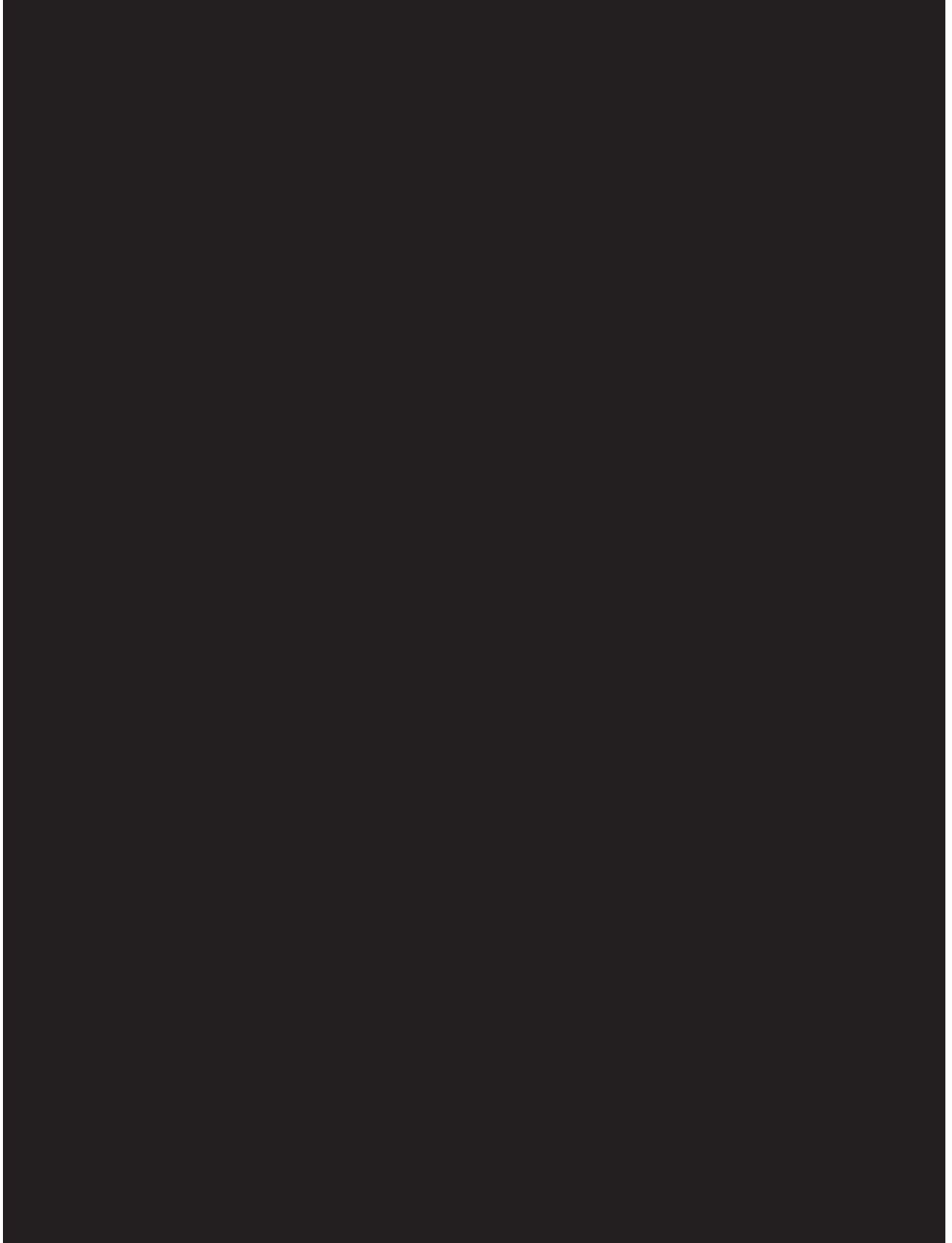
Page 3
Schmidt/Parnes

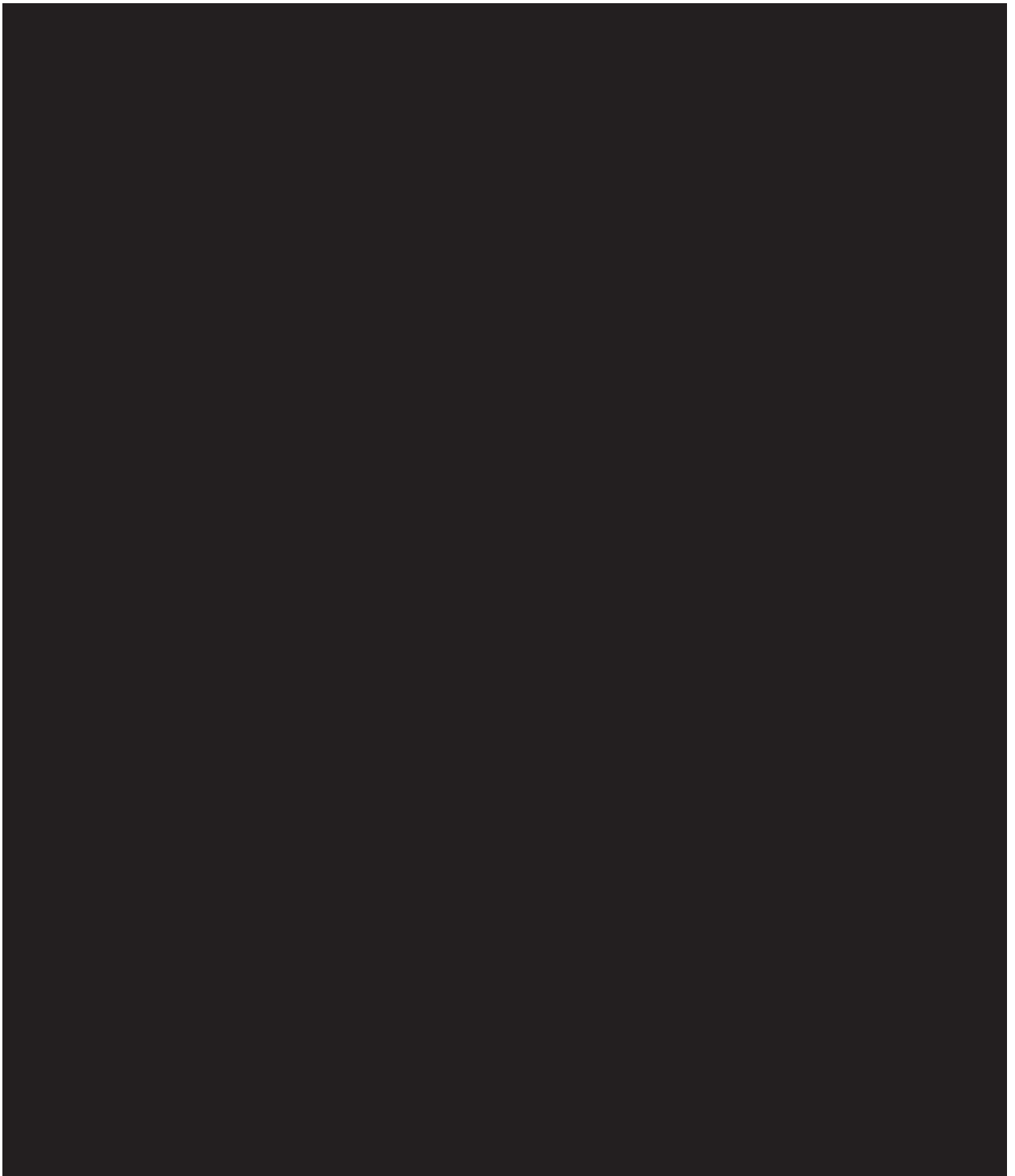
cc:
William Blumenthal, Esq., General Counsel
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Bcc:

M. Glavin (HFC-1)
A. Saben (HFC-200)
D. Mednick (GCF-1)
D. Krawetz (HFC-230)
C. Bechtel (HFD-006)
G. Conley (HFM-650)
V. Toelle (HFV-234)
A. Simoneau (HFZ-300)
J. Welsh (HFS-205)

ATTACHMENT A
FDA CONTACT PERSONS







ATTACHMENT B



EXHIBIT B



UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

WASHINGTON, D.C. 20580

Division of Advertising Practices

April 5, 2011

VIA FEDERAL EXPRESS

VonneFreeda Moore

FDA/CDER Office of Executive Programs, Division of Executive Operations

10903 New Hampshire Avenue

White Oak Building 51, Suite 6100

Silver Spring, MD 20993

Re: POM Wonderful LLC, et al., FTC Docket No. 9344



VonneFreeda Moore
April 5, 2011
Page 2

If you have any questions, please feel free to contact me at 202-326-3115
(mjohnson1@ftc.gov) or my colleague Devin Domond at 202-326-2610 (ddomond@ftc.gov).

Very truly yours,

Mary L. Johnson/NB
Mary L. Johnson

Enclosures





EXHIBIT C



Food and Drug Administration
Rockville MD 20857

May 8, 2008

Jeffrey Schmidt
Director
Bureau of Competition
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Lydia B. Parnes
Director
Bureau of Consumer Protection
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Dear Mr. Schmidt and Ms. Parnes:





Sincerely,

A handwritten signature in blue ink, appearing to read "D. Elder", is written over the typed name.

David Elder
Director
Office of Enforcement
Office of Regulatory Affairs
U.S. Food and Drug Administration

Page 3
Schmidt/Parnes

cc:
William Blumenthal, Esq., General Counsel
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Bcc:

M. Glavin (HFC-1)
A. Saben (HFC-200)
D. Mednick (GCF-1)
D. Krawetz (HFC-230)
C. Bechtel (HFD-006)
G. Conley (HFM-650)
V. Toelle (HFV-234)
A. Simoneau (HFZ-300)
J. Welsh (HFS-205)

EXHIBIT D



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 07 2011

Richard A. Feinstein
Director
Bureau of Competition
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

David C. Vladeck
Director
Bureau of Consumer Protection
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Dear Mr. Feinstein and Vladeck:





Sincerely,

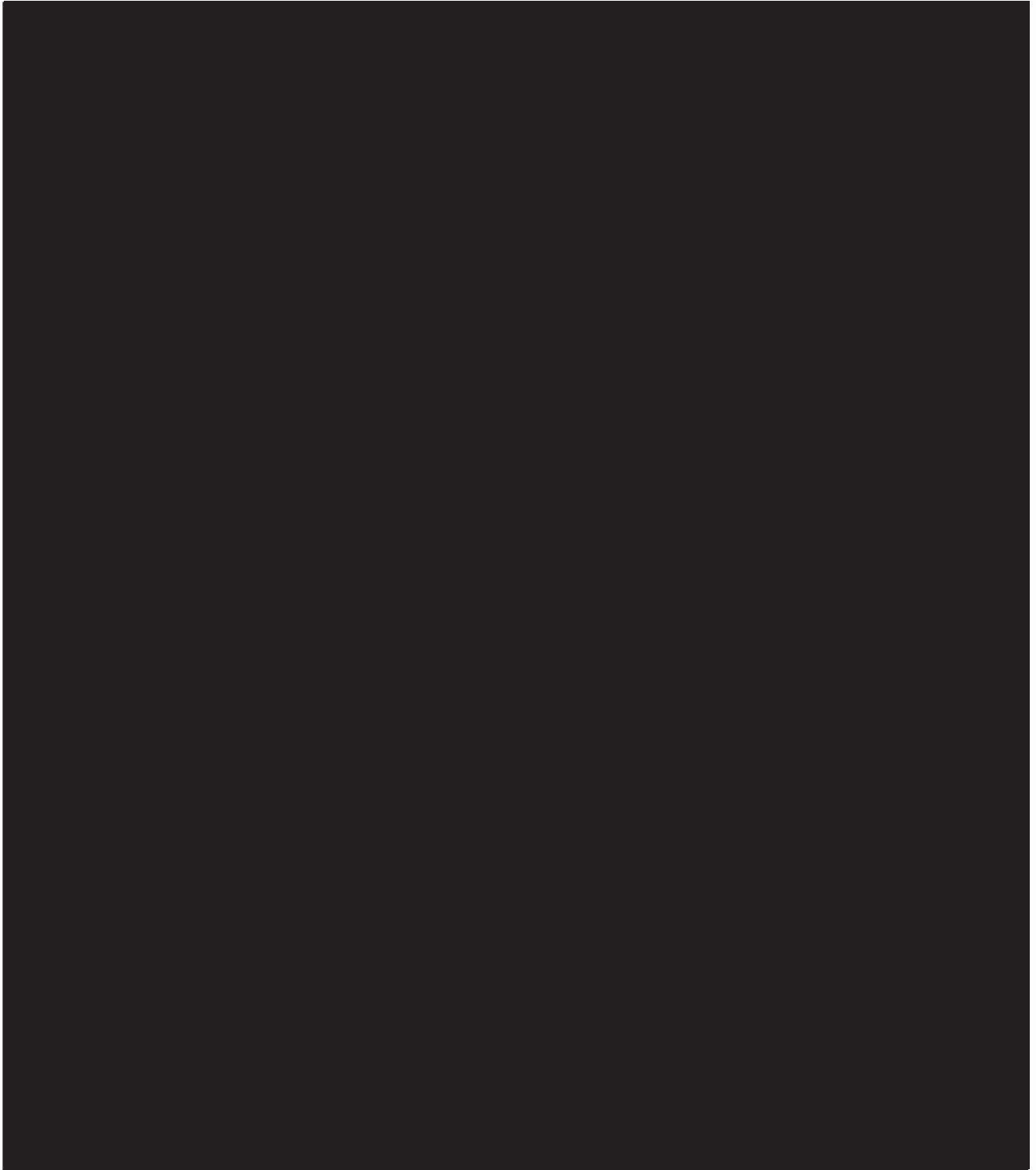
A handwritten signature in blue ink, appearing to read "Howard R. Sklamberg, Esq.", is written over the typed name.

Howard R. Sklamberg, Esq.,
Director
Office of Enforcement
Office of Regulatory Affairs
U.S. Food and Drug Administration

cc:

Willard K. Tom, General Counsel
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

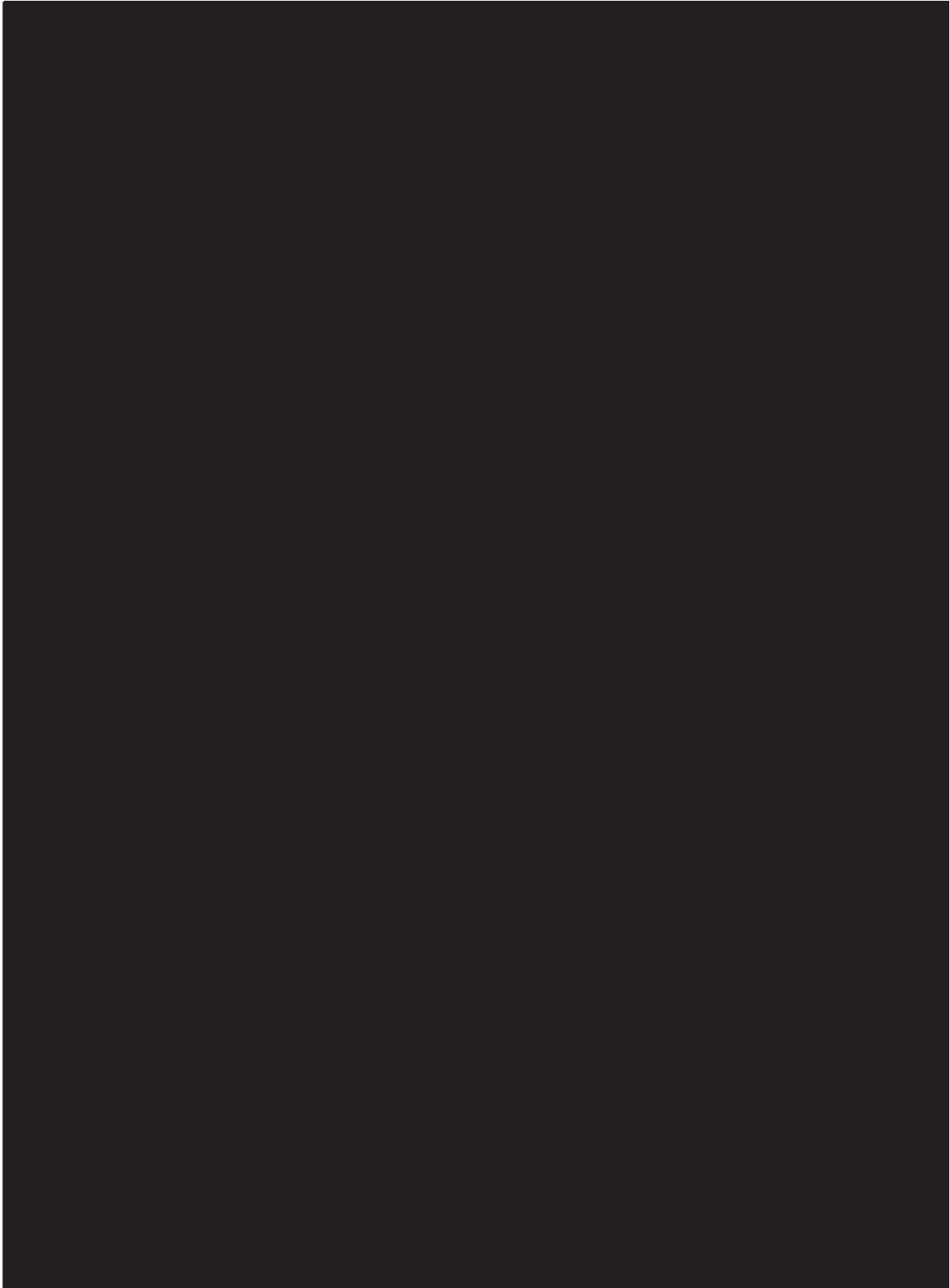
ATTACHMENT A: FDA CONTACT PERSONS







ATTACHMENT B



Bcc:
HFC-230 (Chron, r/f, LDiPaola)
GCF-1 (JTierney)
GCF-1(AWion)
GCF-1(STave)
HFC-230(LDiPaola)
HFD-006(CBechtel)
HFM-650(GConley)
HFV-1(TForfa)
HFZ-300(DWolf)
HFS-615(RWagner)
(KElliott)
(TNguyen)
(RBarror)

EXHIBIT E



UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Division of Advertising Practices

October 21, 2010

VIA EMAIL

Ms. Christine Bechtel
Office of Executive Programs (HFD-006)
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Silver Spring, MD 20993



If you have any questions, please contact me at (202) 326-2934 or at awone@ftc.gov.

Sincerely,

Andrew D. Wone

cc:

VonneFreeda Moore
Public Health Analyst
Division of Executive Operations
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Silver Spring, MD 20993