UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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In the matter of Advanced Bionics, LLC, 12740 San Fernando Road Sylmar, California and Jeffrey H. Greiner, an individual, Respondents.	AMENDED ADMINISTRATIVE COMPLAINT FOR CIVIL PENALTIES FDA Docket: 2007H-0433

Complainant, the Center for Devices and Radiological Health ("CDRH"), Food and Drug Administration ("FDA"), United States Department of Health and Human Services, by Jennifer E. Caruso, attorney for Complainant, respectfully represents as follows:

INTRODUCTION

1. This action is brought by FDA on behalf of CDRH under the Federal Food, Drug, and Cosmetic Act ("the FDCA"), 21 U.S.C. § 333(f),[1] and its implementing regulations, 21 C.F.R. Part 17, which authorize the imposition of civil penalties against persons who violate the FDCA, 21 U.S.C. §§ 301-397, relating to devices as that term is defined by 21 U.S.C. § 321(h), after an opportunity for a hearing provided in accordance with 5 U.S.C. § 554 and 21 U.S.C. § 333(f)(3)(A).

[1] This provision was previously designated as 21 U.S.C. § 333(g), but was recently amended to redesignate subsection (g) as subsection (f). Food and Drug Administration Amendments Act of 2007 (FDAAA), Section 226(b)(1), Public Law 110-85 (Sept. 27, 2007).

2. Advanced Bionics, LLC ("Bionics") manufactures a cochlear implant hearing aid, the HiRes90K Implantable Cochlear Stimulator ("HiRes90K"), which is a device as defined by 21 U.S.C. § 321(h). The HiRes90K is a class III device and requires approval of a premarketing approval application ("PMA").

3. The HiRes90K is designed to provide useful hearing, via electrical stimulation, for individuals with severe to profound hearing loss. The external components of the device include a sound processor, a head piece, and a cable. The internal components of the device include a receiver and electrode array that are implanted surgically under the skin behind the ear. The HiRes90K internal receiver contains a "feedthru" assembly to allow for contact between internal electronic components, which are housed in a hermetically sealed (*i.e.*, moisture-impervious) case, and external components. The device converts sound into electrical energy that activates the auditory nerve. The auditory nerve then sends information to the brain, where it is interpreted as sound.

4. The HiRes90K feedthru assembly contains pins, which form the electrical path between the electrode array and internal electronic components, that are embedded within ceramic beads. The ceramic beads rest on a glass seal. The feedthru assembly is contained within a titanium housing.

5. The HiRes90K is the latest in a series of models of cochlear implants manufactured by Bionics. Bionics first received PMA approval to market cochlear implants for adult use in March 1996, and filed a PMA supplement for the HiRes90K, which FDA approved on July 7, 2003. The PMA supplement for the HiRes90K was the thirtieth (30^{th}) PMA supplement submitted by Bionics for its cochlear implant devices. With each supplement approval, FDA included the following statement as part of the

device's "Conditions of Approval": "Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA ...."

6. In 2001, FDA conducted an inspection of Bionics. The primary manufacturing issue assessed by FDA at that inspection was hermeticity failure, i.e., excessive moisture, in the cochlear implant model marketed by Bionics at that time. At the conclusion of the inspection, FDA issued a List of Inspectional Observations ("FDA-483") listing six objectionable conditions, including the firm's failure to file PMA supplements for four separate testing, manufacturing process, and design changes to its cochlear implants. FDA issued the FDA-483 to Respondent Greiner and discussed the observations with him.

7. On January 14, 2002, Respondent Greiner responded to the FDA-483 in writing. With respect to the observation relating to the firm's failure to file PMA supplements, Mr. Greiner stated that the Bionics would institute a process, effective February 1, 2002, pursuant to which the Regulatory Affairs Department would review and document the PMA supplement filing decision for every document release and device change.

8. Shortly after receiving PMA approval in July 2003, Bionics added another supplier ("Vendor B") for the feedthru assembly for the HiRes90K device. The design of Vendor B's feedthru assembly differed from that of the feedthru assembly that Bionics used to obtain FDA approval of its PMA supplement ("Vendor A's" assembly) in at least three respects: (a) the composition of the glass seal differed between the assemblies, resulting in a different rate of thermal expansion in the glass; (b) Vendor B's feedthru

assembly had a different mechanical configuration to support the ceramic bead; and (c) Vendor B's feedthru had a shorter glass seal. In addition, the glass for Vendor B's feedthru is fired for a different length of time and at a different temperature than Vendor A's.

9. Despite these changes, Respondents did not file a PMA supplement; nor did they file a 30-day notice or a postapproval report informing FDA of the changes.

10. During an inspection from August 25 to September 15, 2004, FDA determined that there was an excessive moisture problem in the HiRes90K. The excessive moisture exposed patients in whom the device was implanted to the risk of device failure that can, and ultimately did, lead to explantation and re-implantation, with the resulting serious risks of surgical intervention, including anesthesia, meningitis, and permanent neurological damage. In addition, excessive moisture can lead to direct current leakage, which may result in permanent injury to the auditory nerve and loss of hearing. At the conclusion of the inspection, FDA again issued a FDA-483 to Respondent Greiner, this time listing twenty-three (23) objectionable conditions observed by FDA investigators. In late 2004, Bionics initiated a recall of unimplanted cochlear implants because of residual moisture problems.

11. On February 1, 2005 FDA sent a Warning Letter to Respondents Greiner and Bionics, discussing the problem of excessive moisture, and noting significant deviations from the current good manufacturing practice ("CGMP") requirements for medical devices set forth in 21 C.F.R. Part 820. On February 18, 2005, Bionics responded to the Warning Letter in a letter signed by Respondent Greiner.

12. Over one year later, on March 8, 2006, Bionics voluntarily initiated a recall of the HiRes90K devices containing feedthru assemblies from Vendor B, because the company had determined that the moisture problem related to the feedthru assembly that it had obtained from Vendor B when it added that supplier in 2003. During a telephone call between personnel at Bionics and FDA on March 15, 2006, the Vice President of Regulatory Affairs for Bionics reported that Bionics had never notified FDA of the addition of Vendor B for the feedthru assembly in the HiRes90K device.

13. After the recall was conducted, Bionics reshipped at least two HiRes90K devices containing Vendor B's feedthru assembly that had been returned to Bionics. These devices were implanted in patients. Four additional such HiRes90K devices were implanted into patients after the recall because Bionics failed to adequately notify the facilities to which these devices had been shipped of the recall. An estimated 3,477 devices with the recalled feedthru assembly were still implanted at the time of the 2006 recall. Of those, an estimated 1,502 devices were implanted in children under 18 years old.

14. FDA conducted an additional inspection of Bionics on February 20-27, 2007, that focused on Bionics' activities related to the March 8, 2006 recall of the HiRes90K device. During that inspection, FDA investigators discussed with Bionics three separate instances of Respondents' failure to file a required PMA supplement for changes to the HiRes90K device, including the failure to seek approval for the changes in the feedthru assembly supplied by Vendor B, as identified in paragraph 8 above.

15. In addition, FDA learned that Bionics qualified Vendor B as a supplier of the feedthru assembly without conducting all of the testing that it conducted with respect to

Vendor A's feedthru assembly when it had sought FDA approval of the HiRes90K device. Specifically, Bionics qualified Vendor B as a supplier for the feedthru component based on helium leak testing, but did not conduct hydrostatic pressure testing or corrosion (soak) testing, both of which involved immersion of the devices in saline solution, or functional electrical testing to assess performance under actual stimulation parameters.

JURISDICTION

16. FDA has subject matter jurisdiction over this action, as delegated by the Secretary of Health and Human Services to the Commissioner of Food and Drugs, and personal jurisdiction over the parties, pursuant to 21 U.S.C § 333(f). Pursuant to 21 U.S.C. § 333(f)(3)(A) and the implementing regulations at 21 C.F.R. pt. 17, the authority to conduct an administrative civil penalty hearing and assess a civil penalty is vested in an administrative law judge, appointed in accordance with 5 U.S.C. § 3105.

RESPONDENTS

17. Respondent Bionics is a corporation that is organized and exists under the laws of the State of Delaware and at all times relevant to this action was doing business at 12740 San Fernando Road, Sylmar, California, 91342. At all times relevant to this action, Bionics was engaged in the business of manufacturing, labeling, promoting, holding, selling and distributing medical devices, specifically HiRes90K cochlear implants, in interstate commerce.

18. At all times relevant to this action, Respondent Jeffrey H. Greiner, an individual, was the President and Co-Chief Executive Officer of Bionics. Mr. Greiner was responsible for, had the authority over, and regularly exercised control over all of the

operations at Bionics, including Bionics' manufacturing, labeling, promoting, holding, selling, and distribution of devices at 12740 San Fernando Road, Sylmar, California 91342.

STATUTORY AND REGULATORY PROVISIONS

19. The FDCA requires that certain class III devices have an approved premarket approval application ("PMA"). 21 U.S.C. § 360e(a). If a change is made to a PMA-approved device that affects its safety or effectiveness, with limited exceptions not applicable to this case, the manufacturer must submit a supplement to the premarket approval application ("PMA supplement") -- and wait for FDA approval -- before implementing that change. 21 U.S.C. § 360e(d)(6)(A)(i); 21 C.F.R. § 814.39.

20. In particular, FDA regulations require manufacturers to submit PMA supplements for changes that affect the safety or effectiveness of the device, including "[t]he use of a different facility or establishment to manufacture" the device, and "[c]hanges in the performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device." 21 C.F.R. § 814.39(a)(3) and (6). Because FDA regulations provide a 180-day time frame for review of, and action on, a PMA supplement for the types of changes set forth above, *see* 21 C.F.R. §§ 814.39(c) and 814.40, such supplements are referred to as "180-day PMA supplements."

21. Changes to *procedures or methods of manufacture* that affect the safety or effectiveness of the device do not require a 180-day PMA supplement as set forth in 21 C.F.R. § 814.39(a) and may be the subject of a 30-day notice to FDA that, *inter alia*, describes the change in detail and summarizes the data supporting the change. 21 U.S.C. § 360e(d)(6)(A)(i); 21 C.F.R. § 814.39(f). A manufacturer may distribute the device so

changed 30 days after FDA receives the notice, unless FDA notifies the manufacturer that the notice is not adequate and a full PMA supplement is required. *Id.* FDA has 135 days to review such a supplement, referred to as a "135-day PMA supplement." *Id.*; *see also* 30-Day Notices and 135-Day PMA Supplements for Manufacturing Method or Process Changes, Guidance for Industry and CDRH at 3, *available at* http://www.fda.gov/cdrh/modact/daypmasp.html (Feb. 19, 1998) ("30-Day Notice Guidance") (stating that changes in design or performance specifications do not qualify for submission of a 30-day Notice and recommending that such changes be submitted as a 180-day PMA supplement). Although FDA expects that it will receive a 30-day notice for changes in suppliers for materials, such a submission is insufficient if the specifications of the material are different. 30-Day Notice Guidance at 3.

22. A manufacturer may make a change to a device without filing a PMA supplement if the change does *not* affect the device's safety or effectiveness and the change is reported to FDA in postapproval periodic reports. 21 C.F.R. § 814.39(b).

23. A device lacking necessary PMA approval (including approval of supplements) is deemed adulterated. 21 U.S.C. § 351(f)(1)(B).

24. A device is also deemed adulterated if the methods used in, and the facilities and controls used for, its manufacture, packing, storage, and installation are not in conformity with the current good manufacturing practice ("CGMP") requirements for devices as set forth in the Quality System Regulation at 21 C.F.R. Part 820. 21 U.S.C. § 351(h).

25. Each introduction of an adulterated device into interstate commerce is a prohibited act. 21 U.S.C. § 331(a).

26. Under 21 U.S.C. § 333(f)(1)(A), with limited exceptions not applicable to this case, any person who violates a requirement of the FDCA relating to medical devices shall be liable to the United States for a civil penalty; however, a person will be liable for a civil penalty for a violation of the CGMP requirements only if such violation constitutes (a) a significant or knowing departure from such requirements, or (b) a risk to public health.

27. Under 21 C.F.R. § 17.2, which sets forth the maximum civil penalties for certain violations of the FDCA, any person against whom a civil penalty is assessed under 21 U.S.C. § 333(f)(1)(A) for device-related violations, shall be liable to the United States for a civil penalty in an amount not to exceed $16,500 for each such violation, and not to exceed $1,100,000 for all such violations adjudicated in a single proceeding.

VIOLATIONS

28. Respondents Bionics and Greiner introduced into interstate commerce, and caused to be introduced into interstate commerce, medical devices that were adulterated:

(a) within the meaning of 21 U.S.C. § 351(f)(1)(B) in that they were class III devices that did not have an approved application for premarket approval in effect pursuant to 21 U.S.C. § 360e(a) because changes were made that affected the safety and effectiveness of the medical devices, and a PMA supplement, or a 30-day notice, was not submitted to and approved by FDA, in accordance with 21 U.S.C. § 360e(d)(6)(A)(i) and 21 C.F.R. § 814.39, prior to the distribution of these devices; and

(b) within the meaning of 21 U.S.C. § 351(h) in that the methods used in, and the facilities and controls used for, their manufacture, packing, storage, and installation were not in conformity with the CGMP requirements. For example, Respondents:

(i) failed to sufficiently evaluate and select Vendor B as a supplier of feedthru assemblies on the basis of its ability to meet specified device requirements, as required by 21 C.F.R. § 820.50(a);

(ii) failed to adequately validate the devices containing Vendor B's feedthru assemblies by testing production lots under actual or simulated use conditions, as required by 21 C.F.R. § 820.30(g); and

(iii) failed, for the two devices shipped after the March 2006 recall (unit 351042 received on June 16, 2006, and unit 350983 received on July 7, 2006, as set forth in paragraph 31 below), to establish and maintain procedures for the control and distribution of finished devices to ensure that only devices approved for release are distributed, as required by 21 C.F.R. § 820.160(a).

29. These CGMP violations constituted a significant and knowing departure from the CGMP requirements because the feedthru assembly supplied by Vendor B was a critical component of the HiRes90K cochlear implant, and suppliers of surgically implanted medical devices and their critical components should be thoroughly evaluated and qualified, and those components adequately validated, to ensure that the devices will be safe and effective. In addition, it is imperative that manufacturers implement adequate controls to prevent recalled devices from being reshipped and implanted into patients.

30. The violations also constituted a risk to public health because excessive moisture in the HiRes90K devices containing Vendor B's feedthrus exposed patients in whom the device was implanted to the risk of device failure and the associated risks of surgical intervention and potential permanent loss of hearing. Devices containing

feedthrus supplied by Vendor B had an explant rate four times as high as devices containing feedthrus supplied by Vendor A.

31. Each of Respondents' shipments of an adulterated device into interstate commerce from the State of California is a separate violation of 21 U.S.C. § 331(a) of the Act. These violative shipments were made after Respondents (1) had been told by FDA that they were not filing PMA supplements as required by law; (2) had promised to correct such violations and establish systems to prevent their recurrence; (3) had assembled the product using the feedthru assembly component supplied by Vendor B (shortly after July 2003, to the best of FDA's knowledge); and (4) had been cited for numerous CGMP violations and conducted a recall because of moisture problem in 2004. The following describes Bionics' shipments of adulterated devices, including two shipments made after Respondents initiated the recall on March 8, 2006:

Shipping Date	**Unit No.**	**Destination**
1/21/2005	25564	Boys Town National Research Hospital, Omaha, Nebraska.
5/19/2005	24202	Medical City Dallas Hospital, Dallas, Texas.
5/24/2005	24208	Penrose St. Francis Hospital, Colorado Springs, Colorado.
5/26/2005	24201	Carle Foundation Hospital, Urbana, Illinois.
6/3/2005	24207	Jewish Hospital Healthcare Network, Louisville, Kentucky.
6/8/2005	24189	Temple University Hospital, Philadelphia, Pennsylvania.
6/29/2005	24197	Phoenix Children's Hospital, Phoenix, Arizona.
7/17/2005	25499	NYU Hospitals Center, New York, New York.
7/21/2005	25549	Boys Town National Research Hospital, Omaha, Nebraska.
7/21/2005	25607	Boys Town National Research Hospital, Omaha, Nebraska.
7/21/2005	25562	Boys Town National Research Hospital, Omaha, Nebraska.
7/21/2005	25601	Boys Town National Research Hospital, Omaha, Nebraska.

7/22/2005	25543	Zale Lipshy University Hospital, Dallas, Texas.
7/22/2005	25603	Medical College of Wisconsin, Wauwatosa, Wisconsin.
7/22/2005	25565	Tampa General Hospital, Tampa, Florida.
7/22/2005	25599	Florida Hospital, Apopka, Florida.
7/22/2005	25570	Zale Lipshy University Hospital, Dallas, Texas.
7/22/2005	25597	Egleston Hospital, Atlanta, Georgia.
7/22/2005	25608	Pitt County Memorial Hospital, Greenville, North Carolina.
7/29/2005	25669	Sinai Grace Hospital, DMC Lasher Ambulatory, Southfield, Michigan.
7/29/2005	25749	Boca Raton Community Hospital, Boca Raton, Florida.
8/5/2005	25514	Tampa General Hospital, Tampa, Florida.
8/18/2005	25505	Baptist Medical Center, Jacksonville, Florida.
8/18/2005	25614	Rocky Mountain Cochlear Implant Center, Englewood, Colorado.
8/19/2005	25646	Yale New Haven Hospital, New Haven, Connecticut.
8/25/2005	25500	East Alabama Medical Ctr., Opelika Alabama.
8/29/2005	25521	Allegheny General Hospital, Pittsburgh, Pennsylvania.
8/29/2005	25544	UNC Hospital, Chapel Hills, North Carolina.
8/30/2005	25524	Tampa General Hospital, Tampa, Florida.
8/30/2005	25533	All Children's Hospital, St. Petersburg, Florida.
8/30/2005	25584	Florida Hospital, Apopka, Florida.
9/8/2005	25556	NYU Medical Center, New York, New York.
9/14/2005	25660	Texas Children's Hospital, Houston, Texas.
9/23/2005	25523	Mayo Clinic Hospital, Phoenix, Arizona.
9/23/2005	25538	St. Vincent's, Littlerock, Arkansas.
9/23/2005	25498	Ochsner Clinic, New Orleans, Louisiana.
9/26/2005	25552	Memorial Hermann Southwest Hospital, Houston, Texas.

9/27/2005	25520	Children's Medical Center, Dallas, Texas.
9/27/2005	25510	Tampa General Hospital, Tampa, Florida.
9/27/2005	25508	Children's Healthcare of Atlanta, Atlanta, Georgia.
9/27/2005	25548	Medical College of Wisconsin, Milwaukee, Wisconsin.
9/27/2005	25553	University of Rochester, Rochester, New York.
9/27/2005	25526	Children's Medical Ctr., of Dallas, Dallas, Texas.
9/27/2005	25583	University of Cleveland, Cleveland, Ohio.
9/28/2005	25611	Virginia Mason Medical Center, Seattle, Washington.
9/29/2005	25497	Children's Healthcare of Atlanta, Atlanta, Georgia.
9/30/2005	25655	VA Medical Center, 423 23rd Street, New York, New York.
10/6/2005	25537	Temple University Children's Hospital, Philadelphia, Pennsylvania.
10/6/2005	25530	Southwest Texas Methodist Hospital, San Antonio, Texas.
10/6/2005	25666	Medical City Dallas Hospital, Dallas, Texas.
11/18/2005	25507	Riley Hospital, Indianapolis, Indiana.
11/18/2005	25653	Riley Hospital, Indianapolis, Indiana.
12/5/2005	25503	Children's Memorial Hospital, Chicago, Illinois.
12/5/2005	25615	Children's Memorial Hospital, Chicago, Illinois.
1/13/2006	28040	University of Utah Hospital & Clinics, Salt Lake City, Utah.
1/19/2006	28044	Caroline Medical Center, Charlotte, North Carolina.
1/19/2006	28070	Albany Medical Center, Albany, New York.
1/20/2006	27984	St. Luke's Hospital of Kansas, Kansas City, Missouri.
1/23/2006	28020	Spectrum Health Downtown, Grand Rapids, Michigan.
1/23/2006	28014	Sarasota Memorial Hospital, Sarasota, Florida.
1/25/2006	28001	Johns Hopkins Listening Center, Baltimore, Maryland.
1/25/2006	28060	Johns Hopkins Listening Center, Baltimore, Maryland.

1/25/2006	28035	Norton Healthcare, Louisville, Kentucky.
1/26/2006	27989	Tampa General Hospital, Tampa, Florida.
1/27/2006	28023	Norton Healthcare, Louisville, Kentucky.
1/30/2006	27994	Ochsner Foundation Hospital, New Orleans, Louisiana.
1/30/2006	28061	St. Johns Regional Health System Springfield, Missouri.
2/1/2006	28021	Boys Town National Research Hospital, Omaha, Nebraska.
2/2/2006	27986	Deaconess Medical Center, Spokane, Washington.
2/2/2006	28033	Medical University of South Carolina, Charleston, South Carolina.
2/2/2006	28064	Fletcher Allen Healthcare, Burlington, Vermont.
2/13/2006	27985	Kaiser Permante Hi Moanal, Honolulu, Hawaii.
6/16/2006 (received date)	351042	Urilla, Canada.
7/7/06 (received date)	350983	Mindeau, Canada.

32. Petitioner seeks to assess civil penalties against each Respondent pursuant to 21 U.S.C. § 333(f)(1)(A), for introducing, and causing the introduction of, devices that were adulterated as described in the preceding paragraphs into interstate commerce, in violation of 21 U.S.C. § 331(a) of the FDCA. Petitioner seeks to assess a civil penalty in the amount of $16,500 for each of the 74 violations for a total penalty of $1,100,000 against each Respondent.

OPPORTUNITY FOR HEARING

33. To obtain a hearing in this matter, each Respondent must, within 30 days of service of this Amended Complaint, file an answer pursuant to 21 C.F.R. § 17.9. The answer must be filed with the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, Maryland 20852. The failure to file an answer within 30 days of service of the Amended Complaint may result

in the imposition of the proposed civil penalty and assessment, as provided by 21 C.F.R. § 17.11. Respondents may retain counsel to represent them in conjunction with this proceeding. Pursuant to 21 C.F.R. § 17.9, Respondents' answer, if filed, must admit or deny each of the allegations made in this Amended Complaint and must include the following: all defenses on which Respondents intend to rely; all reasons (if any) why Respondents contend that the civil penalty and assessment should be less than the amount requested by this Amended Complaint; and the name(s), address(s), and telephone number(s) of Respondents' counsel (if any).

PRAYER FOR RELIEF

Based on the violations described in this Amended Complaint, COMPLAINANT PRAYS THAT:

1. The Presiding Officer enter a finding that each of the allegations in this Amended Complaint is true;

2. The Presiding Officer enter a finding that each Respondent violated 21 U.S.C. § 331(a) by causing the introduction or delivery into interstate commerce of medical devices adulterated under 21 U.S.C. § 351(f)(1)(B), because those devices failed to have an approved PMA supplement that was required for the changes to the device in Vendor B's feedthru assembly and under 21 U.S.C. § 351(h), because the methods used in, and the facilities and controls used for, their manufacture, packing, storage, and installation are not in conformity with the CGMP requirements for devices as set forth in the Quality System Regulation at 21 CFR Part 820;

3. The Presiding Officer enter a finding that the CGMP violations constituted a significant or knowing departure from CGMP or a risk to public health;

4. The Presiding Officer enter a finding that each and every affirmative defense presented by each Respondent is not meritorious;

5. The Presiding Officer enter a finding that each Respondent is liable for civil money penalties pursuant to 21 U.S.C. § 333(f)(1)(A) and 21 C.F.R. § 17.2;

6. The Presiding Officer enter a finding that the appropriate amount of the civil penalty for which each of the Respondents is liable, considering all mitigating or aggravating factors, including the nature, circumstances, extent, and gravity of the violations, Respondents' ability to pay a civil penalty, the effect on their ability to continue to do business, their prior violations, their degree of culpability, and such other matters as justice may require, is $1,100,000 for each Respondent.

Respectfully Submitted,

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DATED: 3/17/09

CERTIFICATE OF SERVICE

I, Jennifer E. Caruso, hereby certify that on the 17th day of March, 2008, I served via FedEx a copy of the Amended Administrative Complaint for Civil Money Penalties in the above-captioned matter to the following persons:

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