DECISION DENYING REQUESTS FOR HEARING AND REQUEST FOR DECLARATION UNDER 21 U.S.C. 1604(b)(3)(A) DOCKET NO. FDA-2019-P-1009

This proceeding of the Food and Drug Administration (FDA or Agency) arises out of a Petition, submitted to the Agency by Eric S. Rossman of Rossman Law Group, PLLC on behalf of his clients, Jeff and Janet Connell (the Petitioners), pertaining to a modular revision hip system implanted into Mr. Connell in April of 2011. Petitioners request that the Agency issue a declaration under the Biomaterials Access Assurance Act of 1998 (BAAA), codified at 21 U.S.C. §§ 1601-1606, that Lima Corporate S.P.A. (Lima Corporate) was required to register with the FDA pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 360, and its implementing regulations, and to include the Modular Revision Hip System that is the subject of the Petition on a list of devices filed with the FDA pursuant to section 510(j) of the Act, 21 U.S.C. § 360(j).[1]

Based on my review of the submissions by Petitioners and Lima Corporate, and for the reasons set forth below, I find that the requests for hearing presented no genuine and substantial issue of fact material to determining whether Lima Corporate was required, in the period from March 3, 2010 (date of marketing clearance of K092331 in the U.S.) to April 2011 (implantation into Mr. Connell), to register with the FDA and list the Modular Revision Hip System with the Agency. Therefore, I deny the parties' requests for a hearing. In addition, I determine, for the

[1] *See* 21 U.S.C. § 1604(b). The BAAA provides, in pertinent part, that any person may petition the FDA for a declaration that states that a "biomaterials supplier," with respect to an implant that allegedly caused harm to the "claimant" was required to "register with the [FDA] under section 360 [of title 21], and the regulations issued under such section, but failed to do so" or was required to "include the implant on a list of devices filed with the [FDA] pursuant to section 360(j) [of title 21] and the regulations issued under such section, but failed to do so." The BAAA defines "biomaterials supplier" as "an entity that directly or indirectly supplies a component part or raw material for use in the manufacture of an implant," *id.* at § 1602(1)(A), and a "claimant" as "any person who brings a civil action, or on whose behalf a civil action is brought, arising from harm allegedly caused . . . by an implant." *id.* at § 1602(2)(A).

reasons set forth below, that Lima Corporate was not required, during the relevant timeframe, to register with the FDA or list the implant at issue under section 510 of the Act.

As the Chief Scientist, I am authorized to perform all delegable functions of the Commissioner of Food and Drugs. I issue this Decision under the BAAA pursuant to the authority delegated to the Commissioner of Food and Drugs from the Secretary of Health and Human Services.

I. Procedural Background

On March 1, 2019, the FDA received the Petitioners' Petition, and acknowledged receipt of same via letter dated March 4, 2019. The FDA accepted and docketed the Petition under docket number FDA-2019-P-1009. Pursuant to 21 U.S.C. § 1604(b)(3)(A), on April 9, 2019, the FDA published a "Notice of Opportunity for Hearing" (NOOH) to docket number FDA-2019-P-1009, and served copies of the NOOH on counsel for Petitioners and counsel for the defendants named in Petitioners pending lawsuit in federal court which alleges claims related to the Modular Revision Hip System: Lima Corporate, Lima USA, Inc., DJO Global, Inc., and Encore Medical, L.P. ("Encore"). The NOOH provided notice of the Petition and an opportunity for any party to request an informal hearing[2] to show why the Agency should or should not issue the declaration requested by the Petition. The NOOH stated that any request for a hearing must be made, in writing, and submitted to the FDA on or before April 30, 2019. Counsel for Petitioners and counsel for Lima Corporate timely submitted requests for hearing to the Agency on April 26, 2019, and April 30, 2019, respectively.

[2] FDA's informal hearing procedures are set forth in Title 21 of the Code of Federal Regulations (CFR), Part 16.

II. Analysis

The Commissioner may deny a request for a hearing, in whole or in part, under 21 C.F.R. § 16.26(a), if the Commissioner, or the FDA official to whom the authority is delegated to make the final decision on the matter, determines that no genuine and substantial issue of fact has been raised by the material submitted.

The standard for denial of a hearing in 21 CFR 16.26(a) aligns with the standard in federal court for summary judgment. *See Hess & Clark, Div. of Rhodia, Inc. v. Food & Drug Admin.*, 495 F.2d 975, 983 (1974) (While discussing an FDA order withdrawing approval of a new animal drug application, the court stated, "When the FDA issues a Notice of Opportunity for Hearing, its summary judgment procedures are available if the requesting party fails to raise material issues of fact."). A material factual dispute is one that would affect the outcome of the proceeding.

Although both counsel for Petitioners and counsel for Lima Corporate requested a hearing in response to the NOOH, neither submission raised a genuine and substantial issue of fact material to determining whether, in the relevant period of March 2010 to April 2011, Lima Corporate was required to register with the FDA and list the Modular Revision Hip System with the Agency, but failed to do so. As discussed below, the terms of the 2009 Supply Agreement ("Supply Agreement") between Lima Corporate and Encore[3] determine the outcome of this proceeding. I, therefore, deny both requests for hearing, and deny Petitioners request for a declaration pursuant to the BAAA, 21 U.S.C. § 1604(b)(3)(A).

[3] The Supply Agreement was attached to the Petition as Exhibit A. Both Petitioners and Lima Corporate reference and rely upon the Supply Agreement to support the arguments in their submissions to the Agency in this proceeding. No party to this proceeding has called into question the authenticity of Supply Agreement, or the veracity or accuracy of the representations and/or agreements contained therein.

A. The 2009 Supply Agreement

In April 2009, Lima Corporate entered into a written Supply Agreement with Encore (doing business as DJO Surgical). Pursuant to the terms of the agreement, Lima (the "Seller") agreed to supply DJO Surgical (the "Purchaser") with "parts that are used in or incorporated into a joint prosthesis system, including without limitation, the Components . . . in accordance with the terms and conditions" of the agreement. Supply Agreement at Section 1.01. The agreement defines "Components" as "parts developed and/or manufactured by Seller and designed for incorporation into joint prosthesis systems." *Id.* at Section 14.02. The Supply Agreement describes Lima as engaged in the design and manufacture of "Components" and Encore/DJO as engaged in the design and manufacture of "the Product ... which shall incorporate the Components." (*Id.* in first and fourth Whereas clauses).

The Supply Agreement also specified that Lima Corporate agreed to manufacture the Components "in accordance with the applicable current Purchaser approved drawings as maintained in the Seller design history file for such Component" and the applicable delivery specifications attached to the Supply Agreement. *Id.* at Section 1.02(a) (stating also that the approved drawings and delivery specifications are known collectively in the Supply Agreement as the "Component . . . Specifications"). Lima Corporate further agreed that it would "not make any material changes to the Component . . . Specifications or Seller's Quality Management Procedures without Purchaser's prior written consent." *Id.* at Section 1.02(b). Pursuant to the Supply Agreement, "[a]ll Components . . . shipped [under the agreement] shall be received by Purchaser subject to inspection and performance testing, if any, to determine the Components' . . . conformity to the Component . . . Specifications." *Id.* at Section 4.01(a). The Supply Agreement therefore

established Lima as a seller of Components for the Encore/DJO Surgical joint prosthesis system for contractual purposes.

The Supply Agreement required Encore/DJO Surgical to obtain, in its name, all regulatory certifications to allow "Purchaser and Seller to sell the Product and all Components" in the United States, "including all FDA clearance letters and 510(k)s." *Id.* at Section 5.01(c). In furtherance of that objective, Lima Corporate agreed to supply "Purchaser with copies of all declarations of conformity, ISO 13485 certifications, copies of or access to review the applicable technical files, design history files, [and] specifications." *Id.*

In accordance with the Supply Agreement, DJO Surgical submitted to FDA, on July 31, 2009, a premarket notification, under section 510(k) of the Act, 21 U.S.C. § 360(k), and 21 CFR part 807, subpart E (Premarket Notification Procedures). The Device Description in the 510(k) described a modular stem, neck (multiple versions), safety screw for stabilization during the implantation phase, and an instrument set for proper implantation. The 510(k) also specified "compatible components" such as femoral heads and acetabular liners that would be necessary for implantation surgery but were cleared under separate 510(k) notifications. The 510(k) included DJO Surgical's methods for packaging each component of the system, product labeling, and sterilization of the packaged and labeled product, among other information. It also included draft Instructions for Use for the Modular Revision Hip Stem System, including instructions that the "stem can be used with either DJO Surgical CoCr or Ceramic femoral heads." The FDA cleared the 510(k) on March 3, 2010, which authorized Encore/DJO Surgical to market and distribute the Modular Revision Hip System in the United States. *See* 510(k) substantial equivalence letter for K092331 and Petition, Exhibit B.

B. Registration and Listing Requirements in the relevant time period

The question to be determined in this proceeding is whether Lima Corporate was required, in the period March 2010 to April 2011, to register with the FDA under section 510 of the Act and its implementing regulations or to list the Modular Revision Hip System with the Agency under section 510(j) of the Act and its implementing regulations. In the relevant time period, FDA's regulations implementing section 510 of the Act exempted certain entities from the Agency's registration and listing requirements, including entities that manufactured devices for another party who both initiated the specifications for the device and commercially distributed the device. 21 C.F.R. § 807.20(c)(1) (2010 and 2011 editions) ("Registration and listing requirements shall not pertain to any person who . . . [m]anufactures devices for another party who both initiated the specifications and commercially distributes the device").

Pursuant to the Supply Agreement, DJO Surgical requested and directed the use of Lima Corporate's specifications for the Components covered by the agreement, established additional delivery specifications and acceptance criteria, and ensured that DJO Surgical had control over the device specifications. DJO Surgical incorporated those specifications and criteria into the premarket notification it submitted to FDA for the Modular Revision Hip System, and obtained a 510(k) clearance for the Modular Revision Hip System from the Agency. As the 510(k) holder, DJO Surgical was legally responsible for the safety and effectiveness of the device and its components, and for the performance of its contract manufacturers. Thus, I find that Lima Corporate "manufacture[d] devices for another party who both initiated the specifications and commercially distribute[d] the device" and was, therefore, not required to register or list under 21 CFR § 807.20 during the relevant time period.

Petitioners also contend that, even if Lima Corporate was exempt from registration and listing under 21 CFR § 807.20, it was nonetheless required to register and list as a foreign exporter pursuant to 21 CFR § 807.40 during the relevant time period. That provision applied to a foreign establishment that "imported or offered for import into the United States" a device that it manufactured. As explained in the preamble to the rule: "This would have foreign establishments comply with the same procedures as domestic establishments." 66 Fed. Reg. 59152 (Nov. 27, 2001). This is reinforced by the preamble, which states that a foreign establishment that supplies components to a U.S. manufacturer that incorporates those components into a device would not be required to register, citing 21 CFR § 807.65. Therefore, I find that 21 CFR § 807.40 did not require Lima Corporate to register or list.

Consequently, based on the Supply Agreement, 510(k) clearance of K092331, and the requirements of 21 C.F.R. §§ 807.20(c)(1), 807.40 and 807.65 in effect in during the relevant time period, I determine that, from March 2010 to April 2011, Lima Corporate would not have been required to register or list because it was exempt from FDA's registration and listing requirements as an entity that manufactured "devices for another party who both initiates the specifications and commercially distributes the device." 21 CFR § 807.20(c)(1) (2010 and 2011 editions). I therefore deny Petitioners' request for a declaration pursuant to 21 U.S.C. § 1604(b)(3)(A).

III. Conclusion

For the reasons set forth herein, I find that there is no genuine and substantial issue of fact material as to whether Lima Corporate was required, from March 2010 to April 2011, to register with the FDA or list the Modular Hip Revision System pursuant to section 510 of the Act and its implementing regulations. Therefore, I deny both requests for hearing. I also find, after reviewing the information submitted by Petitioners and Lima Corporate, the 510(k) clearance for K092331,

and the relevant regulations in effect in during the relevant time period, that from March 2010 to April 2011, Lima Corporate would have been exempt from the Agency's registration and listing requirements pursuant to 21 C.F.R. § 807.20(c)(1) (2010 and 2011 editions). Consequently, I deny Petitioners' request for a declaration pursuant to 21 U.S.C. § 1604(b)(3)(A).

Denise M. Hinton

RADM Denise Hinton
Chief Scientist, Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

Timestamped: 6/28/2019 12:04

SERVICE LIST

Eric S. Rossman
Rossman Law Group PLLC
350 N. 9th Street
Suite 500
Boise, ID 83702
erossman@rossmanlaw.com
Attorney for Petitioners Janet and Jeffrey D. Connell

Stephen R. Thomas
Andrea J. Rosholt
Hawley Troxell Ennis & Hawley LLP
P.O. Box 1617
Boise, ID 83701-1617
sthomas@hawleytroxell.com
arosholt@hawleytroxell.com

Brian J. Hurst
Baker McKenzie
1900 Pearl Street, Suite 1500
Dallas, TX 75201
brian.hurst@bakermckenzie.com

Jeffrey K. Shapiro, Esq.
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W., Suite 1200
Washington, DC 20005-5929
JShapiro@hpm.com
Attorneys for Lima Corporate and Lima USA, Inc.

Joshua S. Evett
Jaclyn Terese Gans
Elam & Burke, P.A.
P.O. Box 1539
Boise, ID 83701-1539
jse@elamburke.com
jtg@elamburke.com

Michael J. Philippi
Lisa C. Sullivan
Nixon Peabody, LLP
70 W. Madison St. Suite 3500
Chicago, IL 60602
mphilippi@nixonpeabody.com
lcsullivan@nixonpeabody.com
Attorneys for DJO Global, Inc. and Encore Medical LP