U.S. FOOD & DRUG ADMINISTRATION

NOTICE OF OPPORTUNITY FOR HEARING
DOCKET NO. FDA-2019-P-1009

April 9, 2019

To Whom It May Concern:

On March 1, 2019, the Food and Drug Administration (FDA or Agency) received a Petition from Jeff and Janet Connell, by and through their legal representative Eric S. Rossman of Rossman Law Group, PLLC, requesting a declaration under the Biomaterials Access Assurance Act of 1998, codified at 21 U.S.C. 1601-1606. On March 4, 2019, FDA accepted the Petition for filing as a procedural matter; such action does not reflect an Agency decision on the substantive merits of the Petition.

The Petition requests that the Agency determine whether, on or before April 2011, Lima Corporate S.P.A. was required, but has failed, (1) 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 or (2) 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). *See* 21 U.S.C. 1604(b).

This letter serves as notice to you, and to all other affected persons, that the Agency has been requested to issue a declaration in response to the Petition which would state that, on or before April 2011, Lima Corporate S.P.A. was required to register with FDA or to list the Modular Revision Hip System with the FDA, but that it has failed to do so. *See* 21 U.S.C. 1604(b)(3). Pursuant to 21 U.S.C. 1604(b)(3)(A)(ii), you are hereby provided an opportunity to request an informal hearing to show why the Agency should or should not issue such a declaration and to raise all issues relating to the determination requested by the Petition. FDA's informal hearing procedures are set forth in Title 21 of the Code of Federal Regulations (CFR), Part 16. Please note that, consistent with procedures at 21 CFR part 16, a request for a hearing may be denied if there are no genuine and substantial issues of fact raised by the material submitted. *See* 21 CFR 16.26. Even if you decide not to request an informal hearing, you may submit written information to assist the Agency in responding to the Petition. Such information should be submitted by April 30, 2019, to John D. Maiers, at the contact information specified below.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

Any written request for a hearing must be made, in writing, on or before Tuesday, April 30, 2019, and submitted via mail, email, delivery service and/or personal delivery to John D. Maiers, Regulatory Policy Analyst, Office of Policy, Center for Devices and Radiological Health, U.S. Food and Drug Administration, WO Bldg. 66, Room 5500, 10903 New Hampshire Avenue, Silver Spring, MD 20993, John.Maiers@fda.hhs.gov. Please reference FDA docket number: FDA-2019-P-1009.

If the Agency receives no request for hearing from a person affected by this proceeding on or before April 30, 2019, then the Agency will issue a final decision on the Petition based on the facts available to the Agency without a hearing.

Sincerely,

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Center for Devices and Radiological Health

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

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