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FDA Begins Reorganization that Will Affect How it Regulates Medical Technology

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The U.S. Food and Drug Administration (FDA) has undertaken significant reorganization efforts this year that affect the way it regulates medical technology. The agency is reorganizing the Office of Regulatory Affairs (ORA) and combining the Office of Compliance (OC) and Office of Device Evaluation (ODE) within the Center for Devices and Radiological Health (CDRH). The agency is making these organizational changes as part of its mission to better ensure patient safety and quality of medical devices in both the pre- and post-market settings.

Changes to the Office of Regulatory Affairs

On 15 May 2017, after four years of planning, the FDA began restructuring ORA from its historical geography-based configuration to a program-based structure, aligning inspectors, compliance officers, and their managers into specialized programs within broader geographical zones. Personnel will be grouped into the following seven product-based categories:

1. Medical Devices and Radiological Health
2. Biologics
3. Import Operations
4. Pharmaceuticals
5. Bioresearch Monitoring
6. Human and Animal Food
7. Tobacco

As a result, ORA's inspection and compliance staff will no longer be organized solely by geography, but will be assigned a specific area of expertise. Accordingly, investigators will no longer have to reach across product categories (e.g., an investigator with food expertise inspecting a device facility), which has sometimes led to inconsistent and unpredictable outcomes. With specialized inspection and compliance staff, FDA hopes that this program realignment will lead to an increased understanding of technology and manufacturing processes by regulators and will result in more consistent and streamlined decision-making, consistent with agency policy. Further, specializing by FDA-regulated product type more closely mirrors the organizational model of FDA's centers and the industries it regulates.

Within the new structure of ORA, the Office of Medical Device and Radiological Health Operations (OMDRHO) has been established to provide advice and counsel to ORA and FDA leadership related to medical device program operations. OMDRHO is directed by Jan Welch—formerly acting director of the CDRH Office of Compliance—and comprises foreign inspections staff, operational staff, and domestic

staff divided into three divisions that conduct inspections and manage compliance activities, recalls, and partnerships (see Figure 1: ORA and OMDRHO Organizational Chart.)

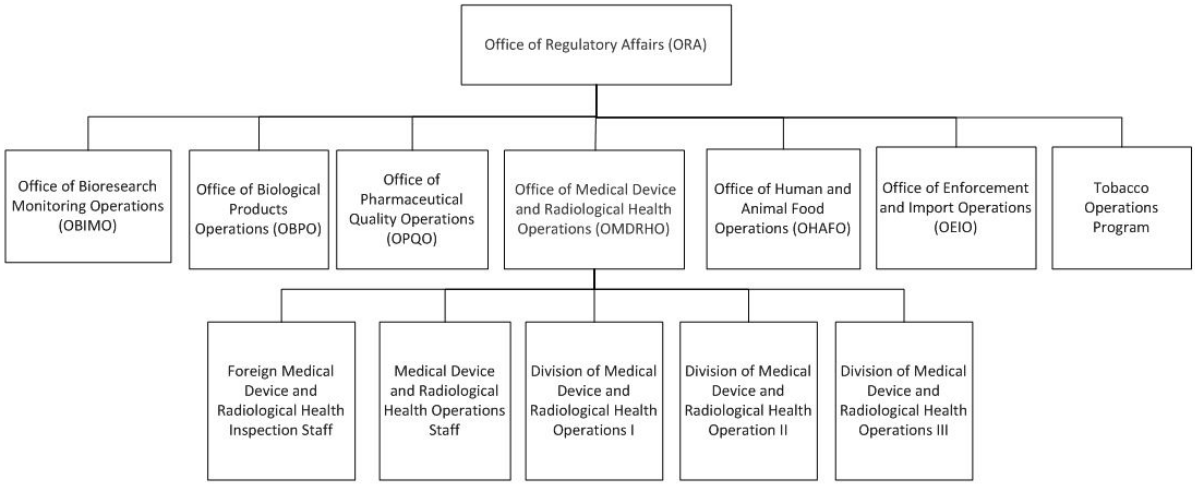

Figure 1: ORA and OMDRHO Organizational Chart

Each Division will be headed by Program Division Directors, formerly District Directors, who are the most senior FDA officials in their geographic area and who will be the point of contact. Joseph Matrisciano is the Program Division Director for Division 1, while the other two Program Division Director positions are vacant as of the date of this client alert.

Each OMDRHO Division covers the geographic area depicted in Figure 2.

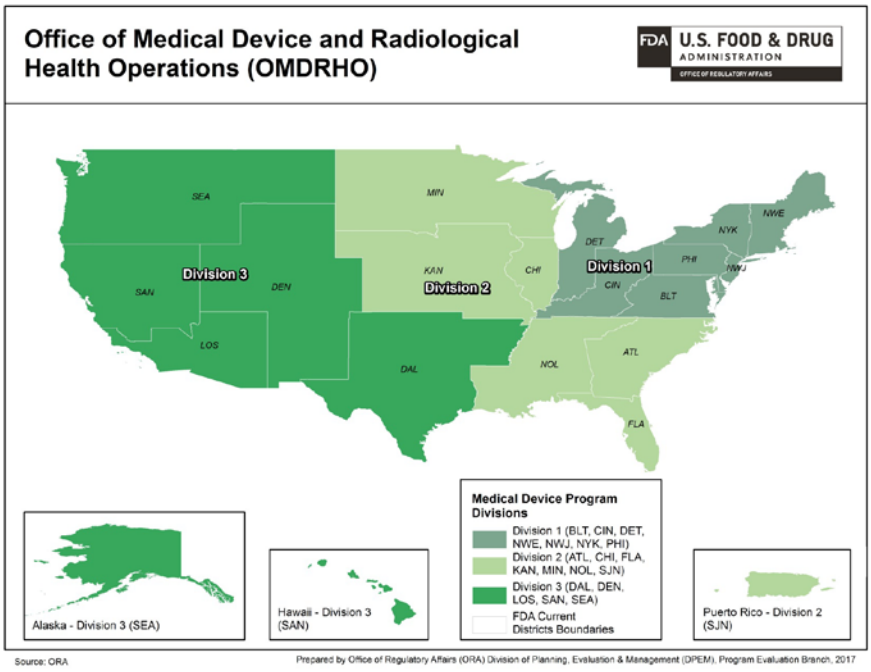

Figure 2: OMDRHO Boundary Map

OMDRHO will partner with CDRH to promote shared strategic priorities and goals and facilitate the development of strategic work plans based on risk and global inventory. The commodity-based model is designed, in part, to allow FDA to gain more intimate knowledge about specific firms and specific device types, and to enhance OMDRHO staff access to, and integration of, total product lifecycle information about devices for which they are responsible. This is expected to yield higher-quality and more consistent assessments and decision-making across industry with respect to compliance actions, such as recalls. Likewise, the realignment may leave FDA better equipped to respond to issues in ways that keep pace with the acceleration of innovation and the expansion of global markets.

The realignment also seeks to address discrepancies between foreign and domestic inspections by making domestic inspections quicker and more efficient. At a 2 May 2017 hearing of the House Energy and Commerce's Subcommittee on Health, CDRH Director Jeffrey Shuren, M.D., J.D., acknowledged that domestic inspections may take longer than foreign ones for a variety of reasons. But, he remarked that program realignment—namely, more training and area-specific expertise for inspections staff—is intended to yield efficiency in facility inspections and should reduce the length of domestic inspections.

Also within ORA, and as a sister office to OMDRHO, the Office of Enforcement and Import Operations (OEIO) covers all imported products, including medical devices; provides direction, assistance, management, and oversight of field import operations, including investigational and compliance activities; and serves as point for headquarters/field relationships on all import programs, operations, and problems. OEIO is also responsible for coordinating agency import activities with U.S. Customs and Border Protection, other federal agencies, and foreign governments with border responsibilities through interagency agreements, memoranda of understanding, and informal working relationships. Existing port of entry import staff will remain in their current locations and are organized into five areas of responsibility to include the Northeast, Southeast, Southwest, Western, and Northern Border Divisions (see Figure 3: OEIO Boundary Map).

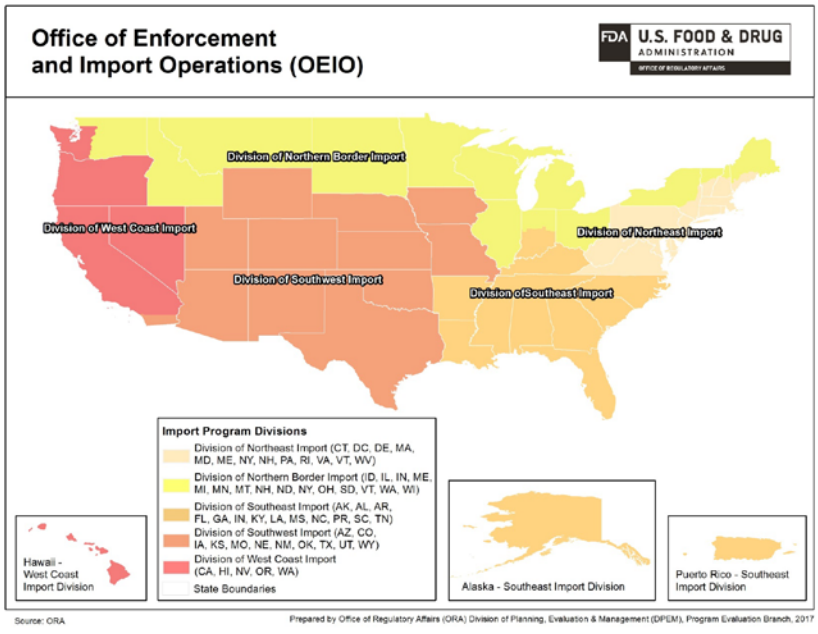

Figure 3: OEIO Boundary Map

OEIO serves a more general enforcement role by providing management and oversight of the Agency's debarment program relevant to FDA compliance. It serves as the clearance point and coordinator for all

administrative warrants and actions, and liaises with ORA and Centers to ensure coordination of evidence. OEIO also oversees all ORA recall operations and health fraud enforcement activities.

Douglas Stearn directs OEIO. He has responsibility for managing operations related to imports, data systems, recalls, and enforcement issues. Mr. Stern was previously deputy director of OC within FDA's Center for Drug Evaluation and Research and director of ORA's Division of Compliance Policy.

Another cross-cutting program office within ORA is the Office of Bioresearch Monitoring Operations (OBIMO), which is responsible for cross-center activities ensuring the protection of subjects involved in clinical research for FDA-regulated products and that non-clinical research is conducted according to Good Laboratory Practices (GLP) requirements. In addition, OBIMO ensures the quality and integrity of data in clinical and non-clinical studies that support the research and marketing applications submitted for review. OBIMO oversees all domestic and foreign Bioresearch Monitoring (BIMO) Program inspectional activity for products regulated by all FDA product centers (see Figure 4: OBIMO Boundary Map).

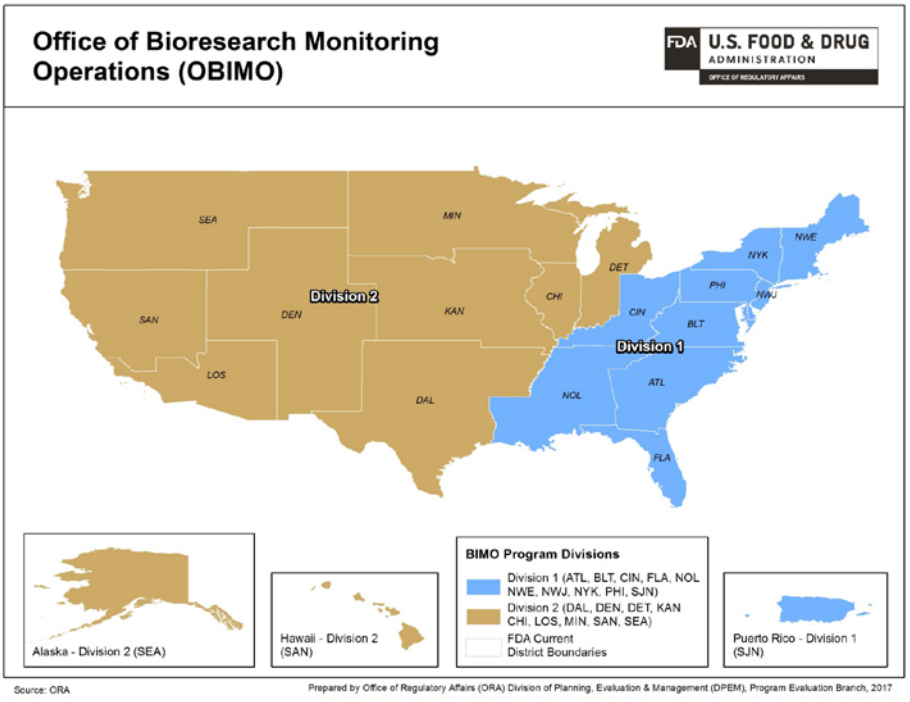

Figure 4: OBIMO Boundary Map

Chrissy Cochran, Ph.D., directs OBIMO's day-to-day operations and coordinates with FDA centers and ORA's Office of Strategic Planning and Operational Policy. Dr. Cochran previously led the Division of Enforcement and Postmarketing Safety in the Office of Compliance in the Center for Drug Evaluation and Research. Prior to that, she led the Good Laboratory Practice compliance program in CDRH.

Although the ORA program realignment has begun, continued operational changes are expected to be implemented throughout 2017.

Combination of Office of Compliance and Office of Device Evaluation

Under FDA's Total Product Life Cycle (TPLC) initiative, FDA has made several changes to group the availability of premarket and post-market information about medical devices. FDA previously instituted a publicly searchable database where information on device clearances and approvals, as well as MDRs and recalls, could be obtained. The TPLC program is now being extended to integrate the OC and ODE to form teams focused on device type. The teams will comprise personnel able to address premarket, bioresearch monitoring, post-market, and compliance issues.

The initiative started in December 2015 with the formation of a cross-center working group. After the working group evaluated various integration models and examined the Office of In Vitro Diagnostics and Radiological Health's 2012 reorganization and integration, FDA formally decided to move forward with the integration program in January 2017. The agency began a pilot program in cardiovascular devices in May 2017, and intends to expand the pilot program to two other product areas later this year. The agency intends to fully implement the reorganization across all divisions in 2018.

As with the reorganization of ORA, the integration of OC and ODE pre- and post-market specialists into teams is designed to increase information-sharing within the agency to ensure consistency, increase FDA knowledge of products and issues associated with the products, and streamline decisions on both pre- and post-market issues.

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