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Top Food and Drug Cases 2015

& Cases to Watch 2016

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SIGNIFICANT AGENCY ACTIONS

by Rikin Mehta and Jennifer S. Hill

The Food and Drug Administration (FDA) played an active role in the food, drug, medical device, and tobacco industries in 2015. FDA took several important steps in bringing new products to market and providing guidance and rules for industry, while continuing to exercise its oversight and enforcement powers.

NEW DRUG APPROVALS

FDA made notable strides with the approval of new products. In 2015, FDA's Center for Drug Evaluation and Research approved 45 novel drugs—new molecular entities under New Drug Applications or as new therapeutic biologics under Biologics License Applications—16 of which were considered first in their class with distinct mechanisms of action.[1] By comparison, on average, FDA approved 28 novel drugs per year between 2006 and 2014.

BIOSIMILARS

2015 saw several noteworthy developments in the emerging field of biosimilars. Enacted in 2010, the Biologics Price Competition and Innovation Act (BPCIA) laid the groundwork for abbreviated regulatory approval of follow-on biologic products that are demonstrated to be "highly similar to the reference product."[2] However, the passage of BPCIA left many unanswered questions about the standards that FDA would apply in evaluating biosimilarity and approving biosimilars for marketing.

FDA took significant steps in providing clarity in this field. On March 6, 2015, FDA broke new ground when it approved Zarxio® (filgrastim-sndz), the first biosimilar product in the United States. Zarxio®, sponsored by Sandoz, is considered biosimilar to Amgen's Neupogen, which was originally licensed in 1991. Shortly thereafter, FDA released a series of guidance documents to provide the industry with valuable information on naming biologic products,[3] scientific and quality considerations in demonstrating biosimilarity to a reference product,[4] and other topics.[5]

NUTRITION AND FOOD LABELING

In June 2015, FDA issued its Final Determination Regarding Partially Hydrogenated Oils (PHOs), through which it announced that PHOs were no longer "generally recognized as safe" or GRAS for human food.[6] In making its determination, FDA cited "the significant human health risks associated with the consumption of trans fat," which is a component of PHOs.[7] Affected entities must comply by June 18, 2018, by removing PHOs from their products or petitioning FDA to permit specific uses of PHOs.[8]

FDA also built upon the proposed rules it announced in 2014 regarding the Nutrition Facts label. In July 2015, FDA issued a proposed rule that would require Nutrition Facts labels to include a declaration of the percent daily value (%DV) for added sugars, similar to the information required for other nutrients such as fats and sodium.[9]

IMPLEMENTATION OF FOOD SAFETY MODERNIZATION ACT (FSMA)

In 2015, FDA finalized five of the seven major rules that implement the FSMA, which was signed into law in 2011. The rules were touted as significant steps towards preventing foodborne illness. In September, FDA issued the first two rules regarding preventative controls for human and animal food.[10] Then, in November, FDA issued its rule on produce safety, which provides standards for growing, harvesting, packing, and holding produce,[11] and two rules on import safety—the Foreign Supplier Verification Programs rule[12] and the Accredited Third-Party Certification rule.[13] The last two rules implementing the FSMA are expected to be finalized in 2016.

Jennifer S. Hill is a partner with Shook Hardy & Bacon in Kansas City, Missouri. She focuses on the defense of pharmaceutical and medical device manufacturers engaged in product liability litigation and advises clients on FDA issues.

FDA ENFORCEMENT

FDA has several enforcement procedures available at its disposal, including seizure, injunction, and debarment. Depending on the nature of the perceived violation, however, FDA may choose to issue a warning letter, which is designed to give individuals and firms "an opportunity to take voluntary and prompt corrective action before it initiates an enforcement action."[14] FDA utilized the warning letters procedures with vigor in 2015. The agency issued 17,232 warnings letters in 2015,[15] nearly double the number of warning letters issued in 2014[16] and more than 25 times the number issued five years ago.[17] The significant majority of warning letters was issued by the Center for Tobacco Products, which was created through authority granted to FDA by the Family Smoking Prevention and Tobacco Control Act, signed into law in 2009.

In addition to warning letters, FDA instituted 21 injunctions, 17 debarments, and one product seizure in 2015.[18]

CONCLUSION

As regulated industries rapidly evolve to meet scientific and healthcare advancements, so too does FDA. In the coming year, manufacturers and firms can expect the agency to continue to take an active role in developing policies and guidance that will shape the food, drug, medical device, and tobacco industries.

ENDNOTES

1 Novel Drugs Summary 2015, available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm474696.htm.

2 *See* 42 U.S.C. § 262(k).

3 Nonproprietary Naming of Biological Products, Guidance for Industry (Aug. 2015), available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery.

4 Scientific Considerations in Demonstrating Biosimilarity to a Reference Product, Guidance for Industry (Apr. 2015), available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM291128.pdf and Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product, Guidance for Industry (Apr. 2015), available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM291134.pdf.

5 Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009, Guidance for Industry (Apr. 2015), available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM444661.pdf, Biosimilars: Additional Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009, Guidance for Industry (May 2015), available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatory Information/Guidances/UCM273001.pdf, and Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants, Guidance for Industry (Nov. 2015), available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM345649.pdf.

6 Final Determination Regarding Partially Hydrogenated Oils, 80 Fed. Reg. 34,650, 34,650 (June 17, 2015).

7 *Id.*

8 *Id.* at 34,653.

9 Food Labeling: Revision of the Nutrition and Supplement Facts Labels; Supplemental Proposed Rule to Solicit Comment on Limited Additional Provisions, 80 Fed. Reg. 44,303 (July 27, 2015).

10 80 Fed. Reg. 55,907 (Sept. 17, 2015); 80 Fed. Reg. 56,169 (Sept. 17, 2015).

11 Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. 74,353 (Nov. 27, 2015).

12 Foreign Supplier Verification Programs for Importers of Food for Humans and Animals, 80 Fed. Reg. 74,225 (Nov. 27, 2015).

13 Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, 80 Fed. Reg. 74,569 (Nov. 27, 2015).

14 FDA Regulatory Procedures Manual, Section 4-1-1, available at: http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176870.htm.

15 FDA Enforcement Statistics Summary, Fiscal Year 2015, available at: http://www.fda.gov/downloads/ICECI/EnforcementActions/UCM484400.pdf.

16 FDA Enforcement Statistics Summary, Fiscal Year 2014, available at: http://www.fda.gov/downloads/ICECI/EnforcementActions/UCM247845.pdf.

17 FDA Enforcement Statistics Summary, Fiscal Year 2010, available at: http://www.fda.gov/downloads/ICECI/EnforcementActions/UCM247845.pdf.

18 FDA Enforcement Statistics Summary, Fiscal Year 2015.