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ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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MEMORANDUM

September 11, 2017

To: Subcommittee on Health Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on "Modernizing FDA's Regulation of Over-the-Counter Drugs"

On **Wednesday, September 13, 2017 at 10:15 a.m., in Room 2322 of the Rayburn House Office Building**, the Subcommittee will consider draft legislation to establish an over-the-counter drug (OTC) user fee program at the Food and Drug Administration and reform of the OTC monograph process.

I. BACKGROUND

A. Over-the-Counter Drugs and the Monograph Process

Over-the-counter (OTC) drugs are drug products that have been found to be safe and effective for use without the supervision of a physician, and can be purchased without a prescription.[1] Examples of OTC monograph drugs include: antacids, antiperspirants, cough and cold products, ophthalmic products, dandruff products, and analgesics.[2] OTC drugs may be approved under a new drug application (NDA) similar to new prescription drugs, or they may be legally marketed without an application through conformance with an OTC drug monograph. An OTC drug monograph details the conditions of use under which active ingredients are generally recognized as safe and effective (GRASE). These conditions of use may include dosage strength, dosage form and route of administration, patient population and indications for use, and required labeling.[3] While OTC drugs subject to a monograph are also subject to inspection and

[1] Food and Drug Administration (FDA), *What are over-the-counter (OTC) drugs and how are they approved?* (https://www.fda.gov/AboutFDA/Transparency/Basics/ucm194951.htm).

[2] FDA, *Overview of the Over-the-Counter Drug Monograph Process* (June 10, 2016) (https://www.fda.gov/downloads/Drugs/NewsEvents/UCM506382.pdf).

[3] *Id.*

compliance requirements, they are not subject to premarket approval if they are in compliance with the monograph.

An OTC drug monograph is established through a three-step public rulemaking process, with each step requiring *Federal Register* publication and a public comment period. As a first step, advisory review panels are convened to review whether the active ingredient of the OTC drug products are GRASE, not GRASE, or require additional data to determine classification. The advisory review panel also reviews claims and recommends appropriate labeling, therapeutic indications, dosage instructions, and warnings.[4] These recommendations are published as an advanced notice of proposed rulemaking (ANPRM) with a 90-day public comment period. As the next step, FDA reviews the panel's recommendations, the public comments, and any new data that may be available, and publishes a tentative final monograph (TFM) regarding the GRASE status. The third step is finalization of the monograph which occurs following FDA's review of public comments and any new data. A final monograph may be amended either by FDA or by petition of any interested person and can be updated to add, change or remove ingredients, labeling, or other pertinent information.[5][6]

B. Issues Associated with the Current OTC Monograph Process

Today, FDA has an estimated 88 rulemakings in 26 therapeutic categories covering over 100,000 OTC drug products, making it one of the largest and most complex regulatory programs at the agency.[7] There are over 800 active ingredients for over 1,400 different uses that FDA is charged with overseeing.[8] However, unlike other regulated product areas, there are no user fees associated with monograph products. The agency employs 30 full time employees (FTEs) for the OTC monograph program, and in 2016, the program had a budget of $8.23 million.[9] For reference, 18 FTEs are devoted to the review of one novel drug application[10], and total PDUFA costs for fiscal year (FY) 2016 were $1.157 billion.[11] Given the small size of the OTC program, the current mandates associated with the Sunscreen Innovation Act, and the recent consent decree on antiseptic rulemaking are consuming more than the majority of the FDA's monograph

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[4] FDA, *Over-the-Counter (OTC) Drug Monograph Process* (https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ucm317137.htm).

[5] *Id.*

[6] FDA, *Public Meeting, Over-The-Counter Monograph User Fees* (June 10, 2016) (https://www.fda.gov/downloads/Drugs/NewsEvents/UCM510584.pdf).

[7] FDA, *Overview of the Over-the-Counter Drug Monograph Process* (June 10, 2016) (https://www.fda.gov/downloads/Drugs/NewsEvents/UCM506382.pdf).

[8] FDA, *Public Meeting, Over-The-Counter Monograph User Fees* (June 10, 2016) (https://www.fda.gov/downloads/Drugs/NewsEvents/UCM510584.pdf).

[9] FDA Presentation to the Hill

[10] FDA, *Frequently Asked Questions: June 10, 2016 Public Meeting on OTC Monograph User Fees* (June 10, 2016) (https://www.fda.gov/Drugs/NewsEvents/ucm500157.htm).

[11] FDA, *FY 2016 PDUFA Financial Report* (https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/FinancialReports/PDUFA/UCM550408.pdf).

program's resources, leaving little capacity or financial resources for work associated with OTC monographs.[12]

In addition, since the current monograph process requires a rule-making process, finalizing or changing the monograph is very burdensome and can take many years. For example, ANPRM for external analgesic drug products was first published in 1979, with a TFM not coming until three years later.[13] This monograph has still not been finalized.[14] ANPRM for the monograph for external analgesic drug products to treat diaper rash was first published in 1982, with the final monograph publication coming ten years later.[15]

The time-consuming nature of the rulemaking process can also make it extremely difficult for the agency to update the monograph to address safety issues. In October 2007, FDA's Pediatric Advisory Committee and Nonprescription Drugs Advisory Committee voted unanimously that adult data on cough and cold products should not be extrapolated to establish efficacy for use of these drug products in children under 12, and that cough and cold products should not be used for children under the age of six.[16] While industry has voluntarily updated labeling on the cough and cold products to reflect that they should not be used by children under the age of four, nearly 10 years later FDA has still not revised the monograph to require updated labeling to reflect the advisory committee's recommendations.

C. OTC Monograph Reform and OTC User Fee Act

FDA has been examining monograph reform and the potential development of a user fee program for some time, holding public meetings in 2014[17] and 2016[18], and public webinars in 2016[19] and 2017.[20] On June 7, 2017, the U.S. Department of Health and Human Services (HHS) transmitted to Congress recommendations to inform the development of an OTC Monograph

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[12] FDA, *The Over-the-Counter Monograph, Presented by Theresa Michele, MD, Director, CDER, DNDP* (2017).

[13] FDA, *Rulemaking History for OTC External Analgesic Drug Products* (https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/ucm155846.htm).

[14] *Id.*

[15] *Id.*

[16] FDA, *Joint Meeting of the Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee* (October 2007) (https://www.fda.gov/ohrms/dockets/ac/07/minutes/2007-4323m1-Final.pdf).

[17] FDA, *Over-The-Counter Drug Monograph System - Past, Present and Future; Public Hearing* (March 2014) (https://www.fda.gov/Drugs/NewsEvents/ucm380446.htm).

[18] FDA, Public Meeting: Over-the-Counter Monograph User Fees (June 10, 2016) (https://www.fda.gov/Drugs/NewsEvents/ucm499390.htm).

[19] FDA, *Over-the-Counter Monograph User Fees – Stakeholder Webinar* (Sept. 6, 2016) (https://www.fda.gov/downloads/ForIndustry/UserFees/OTCMonographUserFee/UCM522112.pdf).

[20] FDA, *Potential Over-the-Counter Monograph User Fees* (https://www.fda.gov/ForIndustry/UserFees/OTCMonographUserFee/default.htm).

User Fee Program. This program would collect user fees to reform the OTC Monograph process, review OTC monographs moving forward through an administrative order process, and support regulatory science development related to OTC monographs.[21] FDA has estimated that $22 million in fees collected under the OTC Monograph User Fee Program would be collected in FY 2018, and would gradually increase to $34 million in FY 2022.[22] HHS also transmitted to Congress proposed performance goals associated with the creation of the OTC Monograph User Fee Program. These goals include: building basic IT infrastructure for the monograph program; timelines and performance goals associated with OTC Monograph Requests for Innovation and meetings; hiring targets; and timelines for safety changes to OTC Monograph Order Requests, among others.

II. LEGISLATION

On September 11, 2017, Reps. Michael Burgess (R-TX), Gene Green (D-TX), Robert Latta (R-OH), Diana DeGette (D-CO), Brett Guthrie (R-KY), and Debbie Dingell (D-MI) released the "Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2017" discussion draft. This discussion draft authorizes the OTC Monograph User Fee Program and includes a number of reforms to the current monograph process, including: transitioning OTC monographs from a rulemaking process to an administrative order procedure; expediting administrative order procedures for OTC monograph drugs that pose an imminent hazard to public health or are associated with serious adverse events requiring safety label changes; outlining a procedure for minor changes to an administrative order for a OTC monograph drug; providing two years of exclusivity for certain OTC innovative changes; and, clarifying how sunscreens would be reviewed moving forward.

The discussion draft will be the focus of the hearing.

III. WITNESSES

Panel I

Dr. Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research
Food and Drug Administration

Panel II

Scott Melville
President and CEO
Consumer Health Products Association

[21] Letter from Thomas E. Price, Secretary of Health and Human Services to Congressman Frank Pallone, Jr. and Congressman Greg Walden (June 7, 2017).
[22] *Id.*

Kirsten Moore
Project Director, Health Care Products
The Pew Charitable Trusts

Michael Werner
Partner
Holland & Knight, on behalf of the Public Access to SunScreens (PASS) Coalition

Gil Roth
President
Pharma & Biopharma Outsourcing Association

Bridgette L. Jones, MD, FAAP
Chair, American Academy of Pediatrics Committee on Drugs
Associate Professor of Pediatrics, University of Missouri-Kansas City School of Medicine