FDA Update 2016

Douglas C. Throckmorton MD
Deputy Director for Regulatory Programs
CDER, FDA

CHPA 2016 Scientific, Regulatory and Quality Conference
May 19, 2016

The opinions and information in this presentation are my own and do not necessarily reflect the views and policies of the FDA

Outline

- Larger context: trends in medical products, including consumer healthcare products
- FDA activities to respond to these trends, illustrating the importance of collaboration
  - OTC Monograph Process Reform
  - Antiseptic Products
  - Abuse and Misuse of OTC medicines

Overall Message

- Development in this area continues to provide new and important self-care products for US public
- Recent activities by FDA and other stakeholders promise important changes in consumer product regulation, development and use
- Continued progress will require continued collaboration to support the timely development of safe, effective and innovative consumer products for the US public

Trends Impacting Medical Product Regulation and Use

- Trend towards individualization of therapies (‘personalized medicine’)
- Trend towards greater interest in transparency of decision-making and in patient involvement
- Continued need to focus on efficient and science-based decision-making
- Focus on public health impact of products as a part of overall benefit-risk assessment
- Expanded access to data, including new kinds of data (e.g., EHR data)

FDA Response to Trends

- Focused FDA attention to areas of high-value in support of public health
- Expanded discussions with outside groups to improve data collection/analysis and decision-making
- Focus on internal processes
- Work to building additional data sources and analytics capabilities in the area of medical products use

EXPLORING OTC MONOGRAPH REFORM AND OTC USER-FEES

Background: OTC Monograph System

- Established in 1972 to address hundreds of thousands of OTC products on the market
- Expert Advisory Panels to review safety and efficacy for classes of products
- Rule-making on conditions of use for products ('GRASE')
- Enables conforming product marketing without marketing application

Background: OTC Monograph System (cont)

- Process of product review is large and complex
  - 88 rulemakings in 26 broad therapeutic classes
  - 800 active ingredients, 1,400 therapeutic uses
  - Changes also require rulemaking
- Process isn't complete for all areas
  - Data inadequacies, resource challenges
- Products are currently on the market, so need to avoid actions that would disrupt availability unnecessarily

Next Steps on OTC Monograph Reform and Potential User Fees

- FDA is working on multiple policy reforms to streamline and modernize the monograph system
- Separately, FDA has a public Meeting June 10, 2016 at FDA's White Oak campus
  - http://www.fda.gov/drugs/newsevents/ucm499390.htm
- Goal of the meeting is to obtain input on potential OTC monograph user-fee program
  - Types of user fees to consider
  - Types of performance goals and measures of success that could be important as a part of such a program

User Fee Program Could Help Address Important Work

- Delays in finalizing monographs
- Delays in responding to urgent safety issues (e.g., acetaminophen safety warnings)
- Difficulties keeping pace with evolving science (e.g., endocrine disruptors)
- Difficulty accommodating innovative products

Key Roles for Outside Groups

- For OTC monograph reform, important that any changes provide transparency and communication and continue to allow for stakeholder comment on regulatory decisions
- For the public meeting to explore user-fees, a docket is posted for comments
- Public meeting is one step in ongoing dialogue between FDA and industry, healthcare groups and consumer groups potentially affected by a user-fee program

ANTISEPTIC PRODUCTS

Antiseptic Products

- Commonly used products
  - Use increasing, particularly in the healthcare setting to prevent nosocomial infections
- FDA re-evaluating the kinds of information needed for the use of the various products
  - Changing science
  - Large, ongoing review of multiple categories
  - Nonprescription Drugs Advisory Committee meetings in 2005 (efficacy) and 2014 (safety)
  - Timeframes set based on consent decree with National Resources Defense Council

Categories of OTC Antiseptics

- Consumer Antiseptics
  - Washes
    - Hand wash (antibacterial soap)
    - Antibacterial body wash
  - Rubs (leave-on products)
    - Hand rubs (hand sanitizer)
    - Antibacterial wipes
- Healthcare Antiseptics
  - Healthcare personnel hand wash or hand rub
  - Surgical hand scrub
  - Preoperative skin prep
- Food Handler Antiseptics
- First Aid Antiseptics

Ongoing Rulemakings

FDA Working with Industry

- FDA has granted several meetings with industry to discuss data requirements and study designs
- Meetings are open to the public and minutes are posted on FDA's website and in the docket
- At industry's request, FDA deferred 3 ingredients from the Consumer Wash final rulemaking to allow additional time to generate needed data

http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm437040.htm

EFFORTS TO PREVENT MEDICATION MISUSE AND ABUSE

OTC Product Misuse and Abuse

- FDA and CHPA share common goals related to reducing misuse and abuse of OTC medicines:
  - Diuretics
  - Laxatives
  - Dextromethorphan
  - Loperamide
  - Cough and cold products in children

Examples of Work to Prevent Medicine Misuse and Abuse

- Work to address drug abuse in all its forms:
  - Partnership for DrugFree Kids
  - Community Anti-Drug Coalition of America (CADCA)
- Work to Support Safe medicine storage and appropriate disposal
  - CHPA actions on issue: UpandAway.org
  - FDA actions on issues: http://www.fda.gov/forconsumers/consumerupdates/ucm101653.htm

Examples of Work to Prevent Medicine Misuse and Abuse (cont)

- Dextromethorphan
  - http://www.chpa.org/DXMTeens.aspx
  - State and private efforts to verify age restrictions to reduce abuse by adolescents
  - Ongoing work by FDA to assess appropriate controls under the Controlled Substances Act ("Scheduling")
- Loperamide
  - "Poor man's methadone" (NY Times)
  - Cardiac arrhythmias reported when abused at high doses
  - Ongoing FDA review

Many Other Shared Interests

- Sunscreens
- NSURE and work to expand non-prescription options for medicines
  - Naloxone
  - Novel Rx to OTC switch programs
- Combination products
  - Pre-filled syringes, metered-dose inhalers

Summary

- FDA is using all of our available tools to address changing trends in the development, assessment, and use of self-care products
- Within our broad range of activities in this important area, our regulatory mission remains at the heart of FDA's work in support of public health
  - FDA will act within its authorities, based on science, in support of our public health mission

Summary (cont)

- Central theme of FDA activities in self-care products is for FDA engagement with stakeholders to address high-value areas to provide new and important products for the US public
- Opportunities exist to improve the timeliness and efficiency of the OTC monograph system
- Success in these areas, and other needed changes to improve OTC product development and use, will require collaboration with many stakeholders

Thank You

- douglas.throckmorton@fda.hhs.gov