FDA Update 2016

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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

• 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
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/officeofmedicallproductsandtobacco/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
  – 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

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