

Nonprescription Drug Safe Use Regulatory Expansion (NSURE)

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FDA 2nd Annual Health Professional Organizations Conference

October 04, 2012

Objectives

- Provide an overview of the new paradigm
- Past and current activities
- Discussion

Current Marketing of OTC Drug Products

- OTC Drug Monographs
 - Ingredient specific
 - No application to FDA required
 - Eg. acetaminophen, diphenhydramine
- Prescription Switch Drug Products
 - Drug product specific
 - New Drug Application required
 - Eg. omeprazole, nicotine, orlistat

Prescription versus Nonprescription

- Under section 503(b)(1)(A) of the FD&C Act (21 U.S.C. 353(b)(1)(A)), a drug must be dispensed by prescription if, “because of its toxicity or other potentiality for harmful effect, or the method of its use, or the **collateral measures necessary** to its use, [it] is not safe for use except under the supervision of a practitioner licensed by law to administer such drug.”

Future of Nonprescription Products

- What should the nonprescription drug market look like in 20 years?
- Can the delivery of information for correct self selection and use be improved?
- How can technology impact self selection and use and expand the availability of certain drug products?
- Can health care providers or technology interventions have a greater role?

Expanding Access

- State allows pharmacies to offer more vaccines.
 - Massachusetts pharmacists can administer 10 adult vaccines in addition to flu vaccine
 - http://articles.boston.com/2012-05-21/metro/31789563_1_flu-vaccines-adult-vaccines-chickenpox
- Emergency Epinephrine in schools.
 - Laws in Virginia and Nebraska require schools to stock epinephrine pens
 - <http://thehill.com/blogs/congress-blog/education/228601-emergency-epinephrine-in-schools-will-save-lives>

Why now?

- Public health need
 - Undertreatment of many common diseases or conditions
- Other reasons
 - Healthcare system
 - People are interested in self selection
 - Differences between generations
 - Dramatic changes in technology

March 2012 Public Hearing

- “Using Innovative Technologies and other Conditions of Safe Use to Expand Which Drug Products Can Be Considered Nonprescription”
 - Notice of Public Hearing: February 28, 2012
 - Meeting held on March 22-23, 2012
 - <http://www.fda.gov/drugs/newsevents/ucm289290.htm>
- Approximately 30 speakers provided broad representation of different views (consumer, professional organizations, academia)
- Panel representation included FDA (CDER, CDRH, CBER) and Center for Medicaid and Medicare Services
- Oral presentations or comments to public docket; docket closed on May 7, 2012

NSURE Concept

- Address the undertreatment of common diseases or conditions by allowing prescription drug products to be available as non prescription through the use of new technologies or other conditions of safe use.
- Conditions of safe use may be:
 - Healthcare providers
 - New technologies

FDA Public Hearing Topics

- Types of Technology and Conditions of Safe Use: Types of conditions, kiosks, which conditions, diagnostic aids
- Pharmacy, Consumer, and Health Care Provider Issues: Types of drugs and conditions, reduce burden on healthcare system
- Other Related Issues: Insurance coverage, out-of-pocket costs, liability, competitive barriers

Important points to clarify

- There may be product-specific conditions of safe use for the new paradigm
- Conditions of safe use may assist in self diagnosis, self selection and the use of the product
- Supported by consumer studies
- Supported by data
- The approvability of a Rx product to OTC with a condition of safe use will be based on the safety profile, and other factors under its approval

Next Steps

- The comments to the docket are being reviewed
- Clarify misconceptions about the proposed paradigm.
- Continue to engage stakeholders through future public meetings



Discussion