DDM

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date 3-19-08
Publication Date 3-20-08
Certifier A. Corbin

Food and Drug Administration

[Docket No. FDA–2008–N–0120]

Standards for Standardized Numerical Identifier, Validation, Track and Trace, and Authentication for Prescription Drugs; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is seeking information and comments on issues related to standards for identification, validation, tracking and tracing, and authentication for prescription drug products. Particularly, we are requesting information and comments from drug manufacturers, distributors, pharmacies, other supply chain stakeholders, foreign regulators, standards organizations, and other Federal agencies and interested parties. This request is related to FDA's implementation of the Food and Drug Administration Amendments Act of 2007 (FDAAA).

Elsewhere in this issue of the **Federal Register**, FDA is publishing a related document entitled "Technologies for Prescription Drug Identification, Validation, Track and Trace, or Authentication; Request for Information."

DATES: Submit written or electronic comments by [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.Regulations.gov.*

oc0841

N

FOR FURTHER INFORMATION CONTACT: Ilisa Bernstein, Office of Policy, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360, e-mail: *ilisa.bernstein@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On September 27, 2007, FDAAA (Public Law 3580) was signed into law. Section 913 of this legislation created section 505D of the Federal Food, Drug, and Cosmetic Act (the act), which requires the Secretary of Health and Human Services (the Secretary) to develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs. Section 913 directs the Secretary to consult with specific entities to prioritize and develop standards for identification, validation, authentication and tracking and tracing of prescription drugs. Section 913 of this legislation also directs the Secretary to develop a standardized numerical identifier which, to the extent practicable, shall be harmonized with international consensus standards for such an identifier, no later than 30 months after the date of the enactment of FDAAA. This standardized numerical identifier is to be applied to a prescription drug at the point of manufacturing and repackaging (in which case the numerical identifier shall be linked to the numerical identifier applied at the point of manufacturing) at the package or pallet level, sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug.

FDA has been engaged in an intense effort to address counterfeit drugs for several years. In 2004, FDA's Counterfeit Drug Task Force released a report (Task Force Report) outlining a framework for public and private sector actions

that could further protect Americans from counterfeit drugs, including implementation of new track and trace technologies to meet and surpass goals of the Prescription Drug Marketing Act, the Federal pedigree law.

In 2006, FDA issued an update report after conducting a fact-finding effort to determine how much progress had been made toward e-pedigree and electronic track and trace. FDA found that although significant progress was made to set the stage for widespread use of e-pedigree in 2007, this goal likely would not be met. Currently, there is no widespread use of e-pedigree.

Currently, e-pedigree is not in widespread use across the supply chain.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a related document entitled "Technologies for Prescription Drug Identification, Validation, Track and Trace, or Authentication; Request for Information." This related document seeks information from technology vendors and others regarding available and emerging technologies for identification, validation, track and trace, and authentication of prescription drugs, as set forth in 505D(b)(3) of the act.

With this document, as a first step in developing standards under section 505D(b) of the act, we are seeking information from drug manufacturers, distributors, pharmacies, other supply chain stakeholders, foreign regulators, standards organizations, other Federal agencies, and other interested parties related to identification, validation, authentication, and tracking and tracing of prescription drugs. Consistent with the act, it is FDA's preference that such standards be the result of existing private and public sector collaborative standards processes. FDA intends to use the response to these comments to determine the state of standards development in these areas and determine how aggressively it may move forward. Recognizing the importance of uniform

standards as well as the need to allow for updating over time, FDA would consider adopting such standards through a guidance process as quickly as possible.

II. Request for Comments

Please comment on the following questions regarding the development of standards related to section 505D of the act.

A. Standard Numerical Identifier

1. Characteristics

a. Should the standardized numerical identifier contain recognizable characteristics (e.g., National Drug Code number) or be random codes?

b. Should there be a common header for item/product segregation based on product type: biologic, solid oral dosage form, etc.? If so, please elaborate.

c. How can parties in the supply chain ensure that the numbers are unique and are not duplicated?

d. How much value would there be in having the numerical identifier in more than one place for the product (e.g., package and pallet level)?

e. Should the numerical identifier be machine readable, human readable, or both?

f. Should the numerical identifier include the lot number and/or batch number?

2. Standards

a. Do standards currently exist for a standardized numerical identifier of prescription drugs?

1. If so, please describe and comment on their application and use.

2. To what extent do these standards reflect stakeholder consensus?

3. Comment on whether any of these standards should be the standard adopted by FDA.

4. If yes, why? Compare this standard with other standards that exist.

5. If not, is there some aspect that could be changed to make it acceptable as the FDA standard?

6. Has this standard been adopted by other countries?

b. Are standards in development or planned for standardized numerical identifiers of prescription drugs in the supply chain? If so, who is developing these standards and what is the timeline for completion?

c. What are the elements, provisions, and particular considerations that should be included in a standardized numerical identifier of prescription drugs? Please be specific in your response and include examples, where possible.

d. Please comment on implementation of standardized numerical identifiers of prescription drugs in the U.S. supply chain.

e. Please comment on any technical or information technology concerns related to a standardized numerical identifier.

f. Comment on any "lessons learned" from foreign experience with standardized numerical identifiers.

3. Economic Impact

a. What are the usual practices and associated costs that now exist for applying bar codes and other technologies for standardized numerical identifiers on packages and pallets?

b. What are the associated costs for the application, use, and maintenance of standardized numerical identifiers?

c. What are the associated costs or processes for updating the standards as needed?

d. What are the benefits of using standardized numerical identifiers?

4. Harmonization With Other Countries

a. What standards or unique identification systems do other countries have in place, currently under development, or planned for the future? If they are under development, please include a timeline for completion.

b. Comment on any "lessons learned" from foreign experience with standardized numerical identifiers.

B. Standards for Validation

1. Do standards currently exist for validation of prescription drugs?

a. If so, please describe and comment on their application and use.

b. To what extent do these standards reflect stakeholder consensus?

c. Comment on whether any of these standards should be the standard adopted by FDA.

d. If yes, why? Compare this standard with other standards that exist.

e. If not, is there some aspect that could be changed to make it acceptable as the FDA standard?

f. Has this standard been adopted by other countries?

2. Are standards in development or planned for validation of prescription drugs in the supply chain?

If so, who is developing these standards and what is the timeline for completion?

3. What are the elements, provisions, and particular considerations that should be included in a validation standard for prescription drugs? Please be specific in your response and include examples, where possible.

4. Please comment on implementation of validation of prescription drugs in the U.S. supply chain.

5. Please comment on any technical or information technology concerns related to validation.

6. Comment on any "lessons learned" from foreign experience with validation.

C. Standards for Track and Trace

1. Do standards currently exist for track and trace of products in the supply chain, generally?

a. If so, please describe and comment on their application and use.

b. To what extent do these standards reflect stakeholder consensus?

c. Comment on whether any of these standards should be the standard adopted by FDA.

c. If yes, why? Compare this standard with other standards that exist.

e. If not, is there some aspect that could be changed to make it acceptable as the FDA standard?

f. Has this standard been adopted by other countries?

g. If standards are under development or planned for the future, please include a timeline for completion.

2. Do standards currently exist for track and trace of prescription drug products in the supply chain?

a. If so, please describe and comment on their application and use.

b. To what extent do these standards reflect stakeholders consensus?

c. Comment on whether any of these standards should be the standard adopted by FDA.

d. If yes, why? Compare this standard with other standards that exist.

e. If not, is there some aspect that could be changed to make it acceptable as the FDA standard?

f. Has this standard been adopted by other countries?

3. Are standards in development for track and trace of prescription drugs in the supply chain?

If so, who is developing these standards and what is the timeline for completion?

4. What are the elements, provisions, and particular considerations that should be included in a track and trace standard for prescription drugs? Please be specific in your response and include examples, where possible.

5. Please comment on implementation of track and trace for prescription drugs in the U.S. supply chain, including, but not limited to, feasibility, costs, timeline, interoperability, information technology, and data storage.

6. Discuss how the data generated from track and trace should be held, where it should be held, concerns related to data security, and means for access to ensure interoperability for data sharing. What elements should be included in such a standard for data exchange, storage, and interoperability?

7. Comment on any "lessons learned" from foreign experience with track and trace.

D. Standards for Authentication

1. Do standards currently exist for authentication of products in the supply chain, generally?

a. If so, please describe and comment on the application and use.

b. To what extent do these standards reflect stakeholders consensus?

c. Comment on whether any of these standards should be the standard adopted by FDA.

d. If yes, why? Compare this standard with other standards that exist.

e. If not, is there some aspect that could be changed to make it acceptable as the FDA standard?

f. Has this standard been adopted by other countries?

2. Do standards currently exist for authentication of prescription drug products in the supply chain?

a. If so, please describe and comment on the application and use.

b. To what extent do these standards reflect stakeholders consensus?

c. Comment on whether any of these standards should be the numerical identifier standard adopted by FDA.

d. If yes, why? Compare this standard with other standards that exist.

e. If not, is there some aspect that could be changed to make it acceptable as the FDA standard?

f. Has this standard been adopted by other countries?

3. Are standards in development for authentication of prescription drugs in the supply chain?

If so, who is developing these standards and what is the timeline for completion?

4. What are the elements, provisions, and particular considerations that should be included in an authentication standard for prescription drugs? Please be as specific as possible and include examples, where possible.

5. Please comment on implementation of authentication for prescription drugs in the U.S. supply chain, including, but not limited to, feasibility, costs, timeline, interoperability, information technology, and data storage.

6. Comment on any "lessons learned" from foreign experience with authentication.

E. Prioritization

Please comment on the priority for development and implementation of identification, validation, authentication, and tracking and tracing standards.

1. Should certain standards be developed and implemented before others?

2. Should certain standards be developed and implemented concurrently?

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and information. Submit a single copy of electronic comments and information or two paper copies of any mailed comments and information, except that individuals may submit one paper copy. Comments and information are to be identified with the name of the technology and the docket number found in brackets in the heading of this document. A copy of this notice and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

Dated: 3/13/08

March 13, 2008.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 08–????? Filed ??–??–08; 8:45 am]

BILLING CODE 4160–01–S