PROPOSED REENGINEERING OF THE FDA MEDICAL DEVICE REGISTRATION AND LISTING SYSTEM

Presented by

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Today's Agenda

I. Overview of FDA's R&L reengineering concepts

II. Unified systems approach

III. Electronic submission of R&L data, including voluntary provision for supplemental information

IV. Summary of key concepts being considered

I. Overview of FDA's Medical Device R&L Reengineering

- Why FDA needs R&L data
- Problems with the current approach
- Key unmet needs
- Reengineering goals
- Process goals
- FDA's conceptual solution

Why FDA Needs R&L Data

- Plan and conduct appropriate inspections.
- Ensure manufacturers have appropriate marketing clearance for their devices.
- Provide information to assist post-market surveillance.
- Trace/track the ownership (production rights) of marketed devices.
- Locate manufacturers, and processing sites of devices subject to recall or other regulatory action.
- Facilitate international commerce.

Problems with the Current Approach

- Registration and listing data is unreliable.
- R&L does not meet some essential needs.
- R&L data can be difficult to access.
- R&L suffers from multiple submission channels, and multiple data entry.
- R&L processes suffer from delays.
- Inadequate links between R&L data from related establishments.

Key Unmet Needs

- FDA needs *accurate*, *timely* R&L data, particularly for higher-risk devices.
- FDA needs *more detailed* information for higher-risk devices subject to premarket review, but only needs *general* information for lower-risk devices.
- FDA needs the ability to *trace the ownership* (production rights) of higher-risk devices.
- FDA needs information concerning the current *production status* of higher-risk devices.

Key Reengineering Goals

- Improve the quality and usefulness of R&L data received, used, and disseminated by the FDA.
- Make the process easier and more timely.
- Move from paper forms to electronic submission.
- Make R&L data and related information more readily available to industry and the public.

Reengineering Goals

- Require submission of *all* essential information and *only* essential information.
- Register *only* appropriate persons/entities.
- Improve the accuracy of registration and listing data.
- Streamline the collection of registration and listing data.
- Provide for security of electronic submissions.
- Eliminate duplication of efforts within FDA.

Reengineering Goals

- Provide incentives for industry to keep R&L accurate and up-to-date.
- Make data readily available to FDA, industry, and the public.
- Reduce data entry and maintenance costs.

- ***Ultimate goal:*** **A simplified, more efficient system, meeting needs of FDA, industry, and the public**.

FDA's Conceptual Solution

- Single system for registration and listing.
- Refinements to improve data accuracy, reduce burdens.
- Improved timeliness.
- Focus on essential needs.
- Use of WWW for all required submissions and all updates.
- Provide incentives for industry to keep R&L data up-to-date.

II. Overview of Unified System

- Single Unified System
- Simplified System
- Simplified Updating
- Information Collection
- Process Changes - Key Elements

Single Unified System

- Registration and listing merged into a single, simplified system.
- Rapid transition to paperless process, complete in 2005.

Simplified System

- Overall, fewer data elements.
- Information collected varies by the risks posed by the device.
- Reduced need to deal with product codes.
- Clearer explanations of establishment types.

Simplified System

- Unified establishment-type definitions throughout 21 CFR Subchapter H - Medical Devices.
- All related establishments will be linked to a parent company.
- Registration submission timeframe consistent with other FDA Centers (within 5 days).

Simplified Updating

- Real-time updates via WWW
- WWW interface will have on-line help and links to FDA regulatory information, advice.
- Burdens are kept to a minimum.

Information Collection

- Data elements carefully selected, with a streamlined process.
- New: Premarket submission application numbers, sterilization information, e-mail address of official contact.
- Eliminated: Product codes, duplication of elements, routine follow-up inquiries by FDA District Offices.
- Designation of a parent company will facilitate identification of related establishment, products.

Process Changes - Key Elements

- Streamlined process will eliminate difficulties firms have with getting registered, listed, and maintaining accurate data.
- Parent company level registration.
- Single official contact responsible for *all* registrations.
- Delegation of updating authority allowed.

Process Changes: Key Elements

- Improved definitions and explanation of FDA requirements will make it easier for industry to provide correct information.
- Real-time assignment of registration numbers.
- Significant resource savings.

Process Changes: Low-Risk Devices

- Product codes no longer need to be submitted.
- Device listing by medical specialty panel and device class.
- E-mail address will be used for collecting additional information when needed.

Process Changes: High Risk Devices

- Device listing information collection focused on higher-risk devices.
- Captures 510(k), PMA, and PDP numbers (in lieu of product codes).
- Collect information on production status and transfer of ownership.

Questions for Attendees

- Parent company concept.
- Single official contact *vs.* multiple contacts.
- Product code identification problems.
- Information collection via e-mail.

III. Electronic Submission of R&L Data

- FDA proposes to transform R&L into a paperless process.
- All R&L data to be submitted via secure WWW site.
- R&L data to be available on WWW.
- Focus on electronic communication.
- Ability to provide supplemental information at option of firm.

Welcome to the World Wide Web!

- FDA proposes to use a WWW interface to collect and update R&L information.
- FDA, industry, and public will have rapid access to current information.
- You will need —
  - A personal computer or terminal
  - A web browser
  - An ISP or other access to the WWW

Key Features of WWW Approach

- Secure site with password protection for submissions and changes to data.
- All (nearly) data will be available for public accessing via the FDA WWW site.
- Update information any time you want.
- WWW interface will have built-in on-line help, built-in error detection, links to FDA regulatory information and advice.
- Voluntary provision of supplemental information on firm, establishments, and products.

Voluntary Submission of Supplemental Information

- Firms that submit R&L data through the WWW may voluntarily provide supplemental information.
- FDA *does not* require this information.
- FDA will make supplemental information available via WWW as a public service.

Supplemental Information

FDA is considering accepting four categories of supplemental information —

- Important public health information.
- Certain information concerning the firm.
- Some establishment information.
- Some product information.

Supplemental Information: Important Public Health Information

- Recalls, market withdrawals, offers to repair, replace, or refund.
- Safety alerts, public health advisories, public heath notices, or other communications concerning a device.
- Changes made to labeling to improve safety.
- Contact for additional information.

Supplemental Information: Information on the Firm

- General information concerning the firm.
- General information concerning the types of medical devices manufactured, processed, or distributed by the firm.
- Contact for additional information concerning the firm and its products.

Supplemental Information: Concerning an Establishment

- Information concerning the capabilities of the establishment.
- Contact for additional information.

Supplemental Information: Product Information

Specific categories of information will vary depending on whether a device is specifically listed or listed only by panel/class. May include:

- Universal Product Numbers.
- Model numbers and catalog numbers.
- Bibliography of studies.
- Summary of safety and effectiveness.
- Information on adverse events.

Internet? WWW? *What's that?*

- Temporary exemptions will permit smooth transition to WWW.
- Easy one-time, one-year exemption.
- Renewable one-year hardship exemptions.
- Sunset: All exemptions will expire in 2005.
- *Note* — FDA District Offices will have terminals available for R&L data entry.

Questions for Attendees

- Current use of WWW, Internet.
- Non-users: Obstacles to use of WWW, Internet.
- General reaction to using WWW to submit, update R&L data.
- Time frame for adapting to WWW.
- Voluntary submission of supplemental information.

IV. Summary of Concepts

- Meets all essential needs.
- Accurate, timely, reliable R&L data.
- Simpler, more understandable system.
- Simpler FDA, industry, and public access to R&L data and related information.
- Eliminates duplication of efforts within FDA.
- Enables more focused, efficient inspections.
- Long-term resource savings to FDA and industry.

Benefits

Industry —

- Will be able to verify R&L data, motivated to keep it up-to-date.
- Will receive new registration number more rapidly.
- Will find the system’s simplified requirements easier to understand.

Benefits

Industry —

- Won’t be faced with repeated submission of the same data.
- Will experience fewer unnecessary import detentions.

Benefits

The public and health professionals —

- Will have easy access to registration and listing information, UPNs, and company WWW sites for additional information.
- Will provide feedback that will help ensure R&L data is accurate.

Conclusion

- The proposed reengineered process will significantly improve data quality and usefulness.
- Implementation will require FDA and industry effort over a period of time.
- FDA and industry will reap significant long-term benefits.

Questions from Attendees

Contact Information

Submit additional questions, comments, and suggestions to —

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