

SESSION V - Update on IT Initiatives

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SmartLabels

- ▶ Electronic submission of label content
 - ▶ Receive, validate, & review of label content
 - ▶ Issue decision and make label content available
- ▶ Primarily focus on structured label content, rather than format
 - ▶ Structured content refers to information or content that has been broken down and classified using metadata
 - ▶ Label format reviewed for visual and graphical requirements (e.g., bee box)
- ▶ EPA partnering with FDA
 - ▶ Building on FDA's structure product labeling success
 - ▶ Drafting XML specification, vocabularies, and validation rules
- ▶ Targeting pilot late summer 2014
 - ▶ Actively seeking input from stakeholders and regulatory partners

Electronic CSPS

- ▶ Confidential Statement of Product Specifications (CSPS) is a consolidated and harmonized version of EPA's CSF and Canada's Specification form
 - ▶ EPA and Canada's PMRA identified the need for a consolidated form during 2011 product chemistry workshop
 - ▶ Developed as an Action item under the U.S. - Canada Regulatory Cooperation Council (RCC)
 - ▶ Harmonizing will allow applicants to submit a similar form to both agencies
- ▶ Electronic tool will assist registrants in filling out CSPS, submit electronically to PMRA and EPA
 - ▶ EPA conducted an internal pilot using the CSPS paper form and CSFs of products
 - ▶ Planning to allow the current CSF form to be submitted on paper while conducting a voluntary pilot for the eCSPS
 - ▶ Preliminary work is underway to identify a common IT approach that is usable by both EPA and PMRA

Endangered Species Assessment Knowledge Database

- ▶ Database with searchable life history and biological information for listed species
- ▶ Includes repository to store referenced publications
- ▶ Listed Terrestrial Animals
 - ▶ Species-specific body weights, diets, obligate relationships, habitat descriptions and elevation restrictions
- ▶ Listed Terrestrial Plants
 - ▶ Species attributes are currently being gathered for the 435 terrestrial plant species found within the lower 48 states
 - ▶ Initial data collection is 90% complete
- ▶ Interagency Data Sharing
 - ▶ EPA in discussions with USFWS to share ESA Knowledge Database to help populate their finer scale species location database
 - ▶ Pilot collaboration starts with roughly 50 species in Arizona

Registration Submission Milestone Tracker

- ▶ Automated emails sent to registrants for seven key milestones
 - ▶ Integrated with internal workload tracking
 - ▶ Registrant must supply email address for each application to receive notifications
 - ▶ Phase 1 implemented January 1, 2014
 - ▶ EPA will work with stakeholder workgroup to identify desired Phase 2 implementation
- ▶ Bundling capability implemented
 - ▶ Single email per milestone for related decisions (e.g., new AI and multiple end use products)