Center for Veterinary Medicine:

Update on the STARS System
and
Electronic Submissions System

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ADS Fall 2001 meeting with CVM
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Goals for Data Management

- Interconnectivity among data applications
  - Within CVM and FDA
- Electronic submissions
- Integrated reviewer interface
- Knowledge management
- Efficiency and quality of review activities
- More data availability on CVM Home Page

CDP System

- CDP (Corporate Database Portal)
  - CVM-wide access to information
  - STARS, DERS, Drug Products Listing
    - Data coordination among applications
  - Oracle 6i applications, Oracle 8i server
    - Step toward Web availability
    - Enables more efficient and integrated review process
  - Upgrade to portal technology
    - Access to FDA data applications

STARS: Recent Upgrades

- Submission Tracking and Reporting System
  - Submission sub-classifications
    - CBE module (FDAMA)
    - Technical sections
    - Pre-submission conferences
  - INAD amendments
  - Reports generation for Web

STARS: New Development

- Submission Tracking and Reporting System
  - Manufacturing information module
    - Connection to ORA's FACTS
  - Formulation module
  - Bio-research Monitoring module
  - Management production reports

DERS: Recent Upgrades

- Drug Experience Report System
  - On line reviews for complete DER
    - Marketed quantity, labeling, ADE
    - Distributor and trade name data maintenance
    - Draft letter with automated archiving of final
  - Automated assignment of reviews
  - Management reports
  - Reports generation for Web

DERS: New Development

- Drug Experience Report System
  - ADE upgrades
    - VEDRA dictionary
    - Reviewer interface improvements
  - Access to label images
  - Additional management reports
  - Additional letter templates

DPL: New Developments

- Drug Product Listing
  - Moving from stand-alone, single-user application
  - Incorporated into Corporate Database
  - Sharing data dictionaries with STARS
- Future Development
  - Communication with CDER's system

Electronic Submissions

- CVM Program
  - First email prototype in the FDA
    - Simplicity and off the shelf
- Agency Cooperation
  - Participating in formulation of Agency guidelines
  - Adopting Agency initiatives
  - Upgrading Agency prototypes

eSubs: Program Inception

- Started email submissions with drug shipments
  - CVM has received over 3000 electronic NCIEs since 1997
- Prototype program
  - PDF Attachment to formatted email message
    - Flat PDF file
  - Manual processing for STARS database logging
  - Manual notification of reviewer by email
  - Models the paper process

eSubs: Recent Expansion

- Expanded to other info in February 2001
  - Meeting Requests, Final Disposition, Slaughter Notices
  - Flat PDF file
- Smart forms available in June 2001
  - All four types of email submissions
  - Adds QC at industry point
  - Automatically logs submissions and forwards for review
  - Automated notification of receipt and errors
  - Upgraded reviewer interface

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Veterinary Medicine

NOTICE OF CLAIMED INVESTIGATIONAL EXEMPTION

Form Approved: OMB No. 0910-0117
Expiration Date: 1/31/02

PAPERWORK REDUCTION ACT STATEMENT: A Federal agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a current valid OMB control Number. The public reporting burden for the collection of information is estimated to vary from 15 minutes to 2 hours, with an average of 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary information, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information to the Food and Drug Administration, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

Submit this notice electronically to:
Food and Drug Administration
Center for Veterinary Medicine (HFV-110)
7500 Standish Place
Rockville, Maryland 20855
(E-mail:cvmdcu@cvm.fda.gov)

DATE: **02/02/2002**
INAD / IFA NO: **I INAD 123**
STUDY / TRIAL ID: **Study 1**
DRUG SHIPMENT NO: **Number of this shipment**
TYPE OF SHIPMENT: ☐ Initial ☐ Supplement ☐ Discontinued ☐ Other

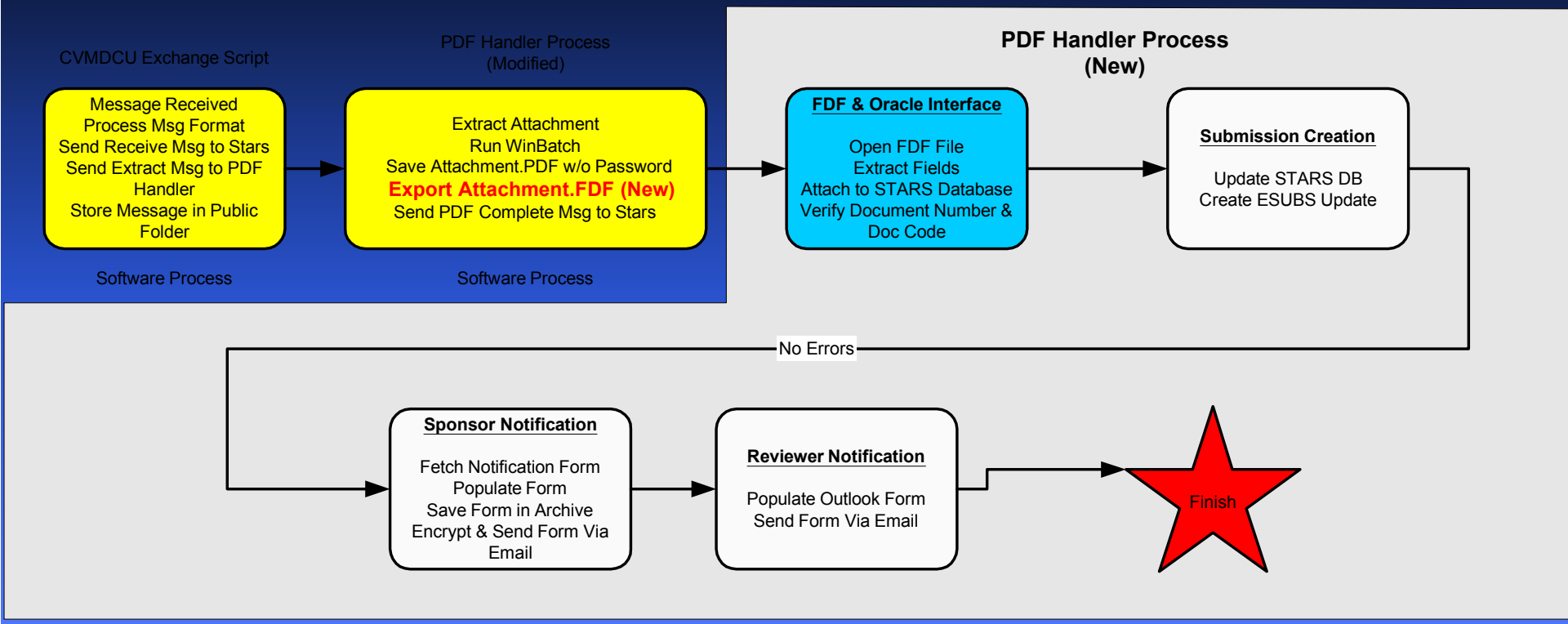
The sponsor, **Water Retention Inc.**, submits a notice of claimed investigational exemption for the shipment or delivery of a new animal drug under the provisions of 21 CFR 511.1. This information is submitted in electronic form.

I. Shipment ☐ or Receipt ☐ Information

Add Password | Mail to | Reset

1. NAME(S) OF THE DRUG(S)
   Established name(s): **Sodium Chloride**
   Trade name(s):
2. PROPOSED USE OF THE DRUG(S): **Water Retention**
3. DATE OF DRUG SHIPMENT (OR RECEIPT): **01/01/2001**
4. TOTAL QUANTITY (WT. OR VOL.) AND CONCENTRATION OF DRUG(S) SHIPPED (OR RECEIVED): **10 pounds**
5. TYPE OF STUDY / TRIAL: **Efficacy**
6. INTENDED USE OF STUDY OR TRIAL: ☒ Pivotal (intended for support of NADA or ANADA) ☐ Non-pivotal
7. NAME AND ADDRESS OF INVESTIGATOR:
   I M Investigator
   100 Main Street

Smart PDF Form Processing



Reviewer Interface for eSubs

ES Reviewer Notification for I-000123-B-0002 - CVM ES Reviewer (Plain Text)

File Edit View Insert Format Tools Actions Form Layout Help

Message | Information

From: CVM PDF Extraction Process

Sent: Tue 2/19/2002 12:51 PM

To:

Subject: ES Reviewer Notification for I-000123-B-0002

CVM Electronic Submissions Reviewer Notification Form

ES Notification Information

Submission ID: I-000123-B-0002

Purpose: P#Study 1/I M Investigator/PA

Document Type: INVESTIGATIONAL NEW ANIMAL DRUG

Submission Type: NOTICE OF SHIPMENT

Drug: CHLORPHENIRAMINE MALEATE

Applicant Information

Applicant: CENTER FOR VETERINARY MEDICI

Submitted: HRrascal@aol.com

Email: HRRascal@aol.com

Correspondence Date: 02/02/2002

Received Date: 02/19/2002

CVM Information

Team: HFV-110

CVM Due Date: 04/10/2002

Meeting Date:

Expedited: N

Final Action Information

Type: NCIE

FNR Reset

FNR/w Memo ACK

Add Attachment

View Information

Submission

Comments History

Sys Message

Commands

Forward | Rqst Concur | Return | Concur | Final Action

Message Text

5.3.12

Electronic Submissions Volume

Sub Type	Total Rec'd	Smart (7/27/01)	Regular (7/27/01)
NCIE	3135	8	275
Meeting	19	12	3
Disposition	15	5	5
Slaughter	3	0	3

eSubs: Initiative 1

- Expanding eSubs to larger, hard-media submissions
  - Reference on Agency docket to accept hard media submissions
    - Currently using CDER guidance as reference
    - Preparing CVM specific guidance
- Process
  - Resource allocated to develop prototype
    - Secure archiving on LAN
    - Tracking in STARS
    - Access through reviewer interface
    - Same performance standards as paper-based submissions

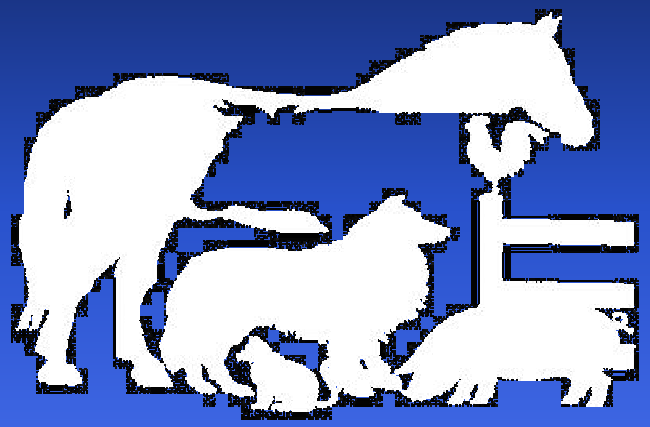
eSubs: Initiative 2

- Expanding eSubs to receive bulk data
  - XML for data in Annual DER reports
    - Adverse Drug Experience periodic reporting
    - Automated data loading for current review module
  - Smart Form 1932 for ADE submissions
  - XML submissions for manufacturing stability data
    - Standards developed in conjunction with CDER
    - Adaptation of CDER's prototype
    - Pre-approval evaluation
    - Post marketing reporting

Electronic Review Environment

- CDMS (Corporate Document Management System)
  - Knowledge management
  - Interface for reviewer processes
  - Workflow modeling and automation
  - Electronic records
  - Electronic signatures
  - Connection to data applications

A View into the Future



- Totally integrated CVM process
  - Pre and post-marketing information
  - Data submitted electronically
  - Data available for review
  - Electronic review
  - Automated workflow
  - Storage and retrieval of information
  - Web-based communication