

M E M O R A N D U M

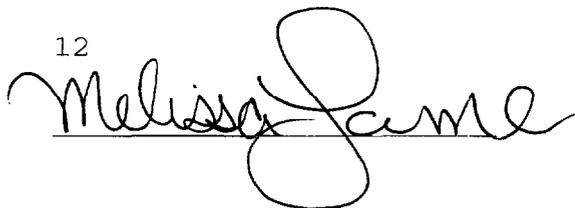
DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

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Date: March 10, 2000
To: Dockets Management Branch (HFA-305)
From: Melissa Lamb
Office of Generic Drugs
Subject: Electronic Abbreviated New Drug Applications

This memorandum forwards overheads of a presentation to the Dockets Management Branch for inclusion in Docket 90S-0308. The following is information on the presentation for the Docket records:

Title of Presentation: Guidance & Current Direction
Presented for: ESD/EVA Advanced Training at UMBC
Date Presented: 3/10/200
Presented by: Richard Sponaugle
Number of Pages: 12


Melissa Lamb

Attachment

90S-0308

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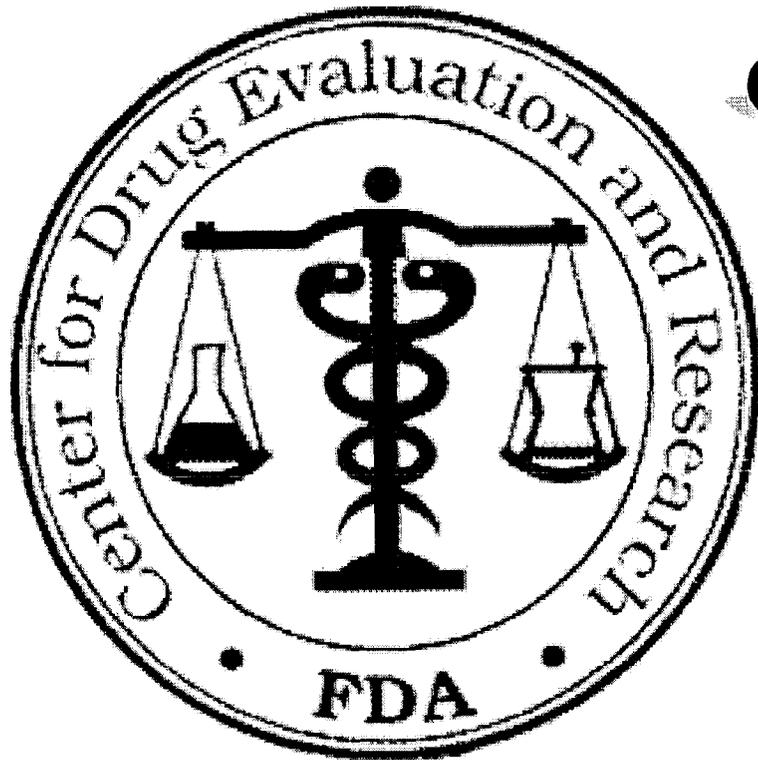
Electronic Abbreviated New Drug Applications

Discussion:

Guidance & Current Direction

Richard Sponaugle

**Senior Systems Engineer,
OGD Electronic
Submission Project,
CDER - FDA**



Electronic Abbreviated New Drug Applications

Guidance for Industry

Preparing Data for Electronic Submission in ANDAs

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
OGD
July 1999

Level Two Guidance:

- Addresses both CMC and bioequivalence
- Covers the program as it now exists
- Will be updated as we move to paperless submissions

Available at:

<http://www.fda.gov/cder/guidance/index.htm>

Electronic Abbreviated New Drug Applications

This guidance is intended to provide assistance to applicants submitting data in electronic format to the Office of Generic Drugs (OGD) in abbreviated new drug applications (ANDAs). This guidance should be used in conjunction with the entry and validation application (EVA) user's manual, available on OGD's electronic submission web site.

When OGD is prepared to archive electronic ANDAs, a guidance will be developed consistent with the Agency's good guidance practices policy (62 FR 8961, February 27, 1997). At that time, information from this guidance will be incorporated into the Agency guidance on electronic regulatory submissions.

Electronic Abbreviated New Drug Applications

What's Covered?

- Basic Rules of Participation
- How to Prepare the Media for Submission
- Where to Send the Submission
- Electronic Submission Tips and Suggestions
- How to Get Additional Help

What's Not?

- Detailed Instructions for Using EVA

Federal Register Notice

Docket No. 99D-5333

**DEPARTMENT OF HEALTH AND HUMAN
SERVICES**

**Food and Drug Administration Plans to Develop
Guidance on Submitting an Archival Copy of an
ANDA in Electronic Format;**

Request for Comments

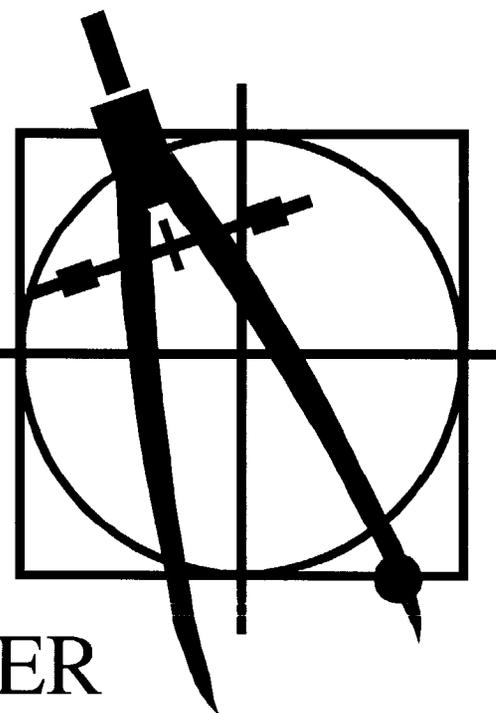
AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Future of Electronic Submissions in OGD

A Better Electronic Submission

- Continued refinement of the structured data elements.
- The addition of a PDF component
- Paperless Archive
- Updates to Existing Guidances
- Web site has been migrated to CDER
- Training will continue to be available at the University of Maryland



The Future of Electronic Submissions in OGD

Continued refinement of the structured data elements.

As we continue to gain experience with the electronic submission system we discover some elements we would like to add to the structured submission and some that we would like to remove.



Harmonization - with New Drug Review Divisions where possible.

The Future of Electronic Submissions in OGD

The addition of a PDF component -Paperless Archive



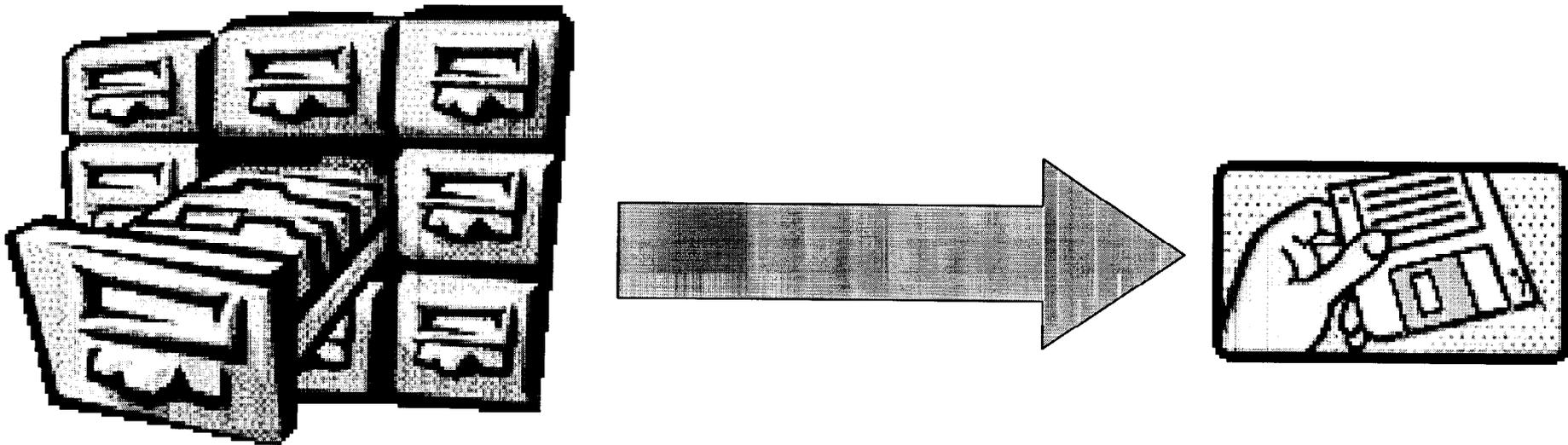
What is PDF?

An acronym for Portable Document Format, PDF is a file type created by Adobe Systems, Inc. that allows fully formatted, high-resolution, PostScript documents to be easily transmitted

across the Internet and viewed on any computer that has Adobe Acrobat Reader software (a proprietary viewer is available for free at the Adobe site).

The Future of Electronic Submissions in OGD

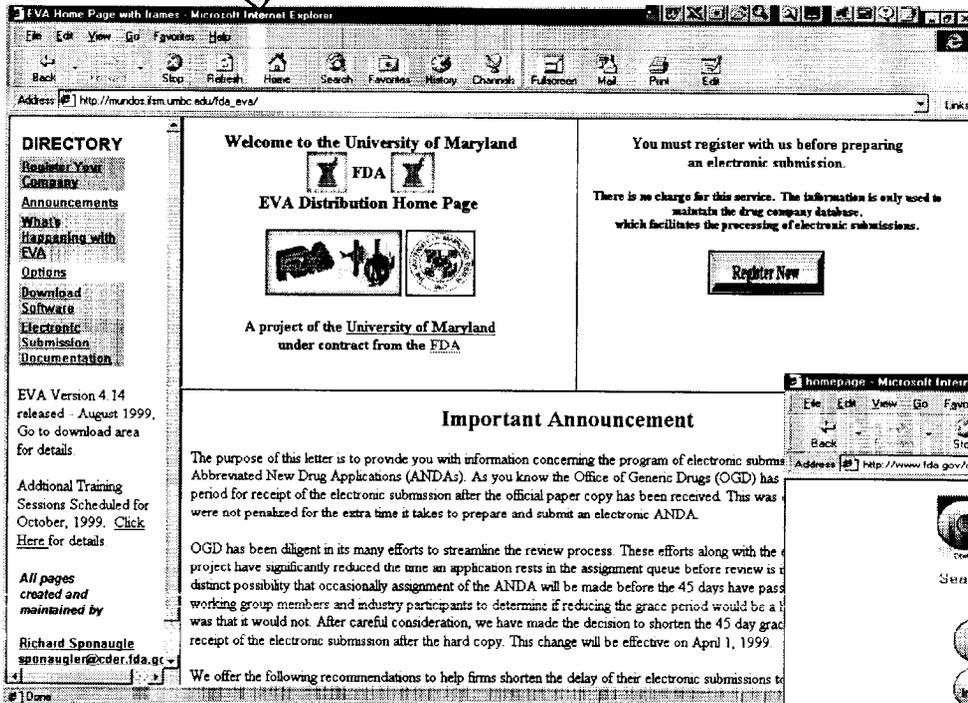
Why Paperless Archive?



Being able to submit and receive information in electronic format in an ANDA is expected to yield many benefits to industry and FDA, including a more consistent submission, a more consistent and rapid review, and a **reduction in archiving and storage space.**

Electronic Submissions in OGD

The Web site has moved to CDER
<http://www.fda.gov/cder/regulatory/ersr/eva/>



EVA Home Page with frames - Microsoft Internet Explorer
Address: http://mundos.ifsm.umbc.edu/fda_eva/

DIRECTORY
[Register Your Company](#)
[Announcements](#)
[What's Happening with EVA](#)
[Options](#)
[Download Software](#)
[Electronic Submission Documentation](#)

EVA Version 4.14 released - August 1999. Go to download area for details.

Additional Training Sessions Scheduled for October, 1999. [Click Here](#) for details.

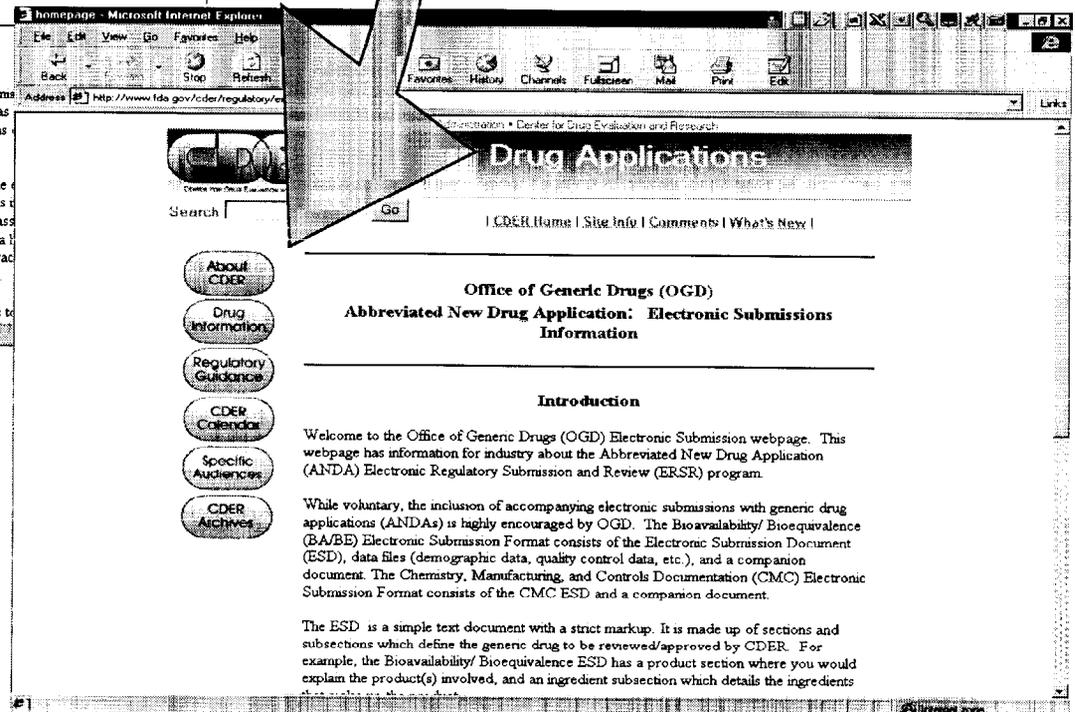
All pages created and maintained by
Richard Spoungle
spoungler@cder.fda.gov

Welcome to the University of Maryland
FDA
EVA Distribution Home Page
A project of the University of Maryland under contract from the FDA

You must register with us before preparing an electronic submission.
There is no charge for this service. The information is only used to maintain the drug company database, which facilitates the processing of electronic submissions.
[Register Now](#)

Important Announcement
The purpose of this letter is to provide you with information concerning the program of electronic submission of Abbreviated New Drug Applications (ANDAs). As you know the Office of Generic Drugs (OGD) has a period for receipt of the electronic submission after the official paper copy has been received. This was not penalized for the extra time it takes to prepare and submit an electronic ANDA.
OGD has been diligent in its many efforts to streamline the review process. These efforts along with the project have significantly reduced the time an application rests in the assignment queue before review is a distinct possibility that occasionally assignment of the ANDA will be made before the 45 days have passed working group members and industry participants to determine if reducing the grace period would be a benefit was that it would not. After careful consideration, we have made the decision to shorten the 45 day grace period of the electronic submission after the hard copy. This change will be effective on April 1, 1999.
We offer the following recommendations to help firms shorten the delay of their electronic submissions to

mundos.ifsm.umbc.edu



homepage - Microsoft Internet Explorer
Address: <http://www.fda.gov/cder/regulatory/ersr/eva/>

CDER
Center for Drug Evaluation and Research

Drug Applications

CDER Home | Site Info | Comments | What's New |

**Office of Generic Drugs (OGD)
Abbreviated New Drug Application: Electronic Submissions Information**

Introduction

Welcome to the Office of Generic Drugs (OGD) Electronic Submission webpage. This webpage has information for industry about the Abbreviated New Drug Application (ANDA) Electronic Regulatory Submission and Review (ERSR) program.

While voluntary, the inclusion of accompanying electronic submissions with generic drug applications (ANDAs) is highly encouraged by OGD. The Bioavailability/Bioequivalence (BA/BE) Electronic Submission Format consists of the Electronic Submission Document (ESD), data files (demographic data, quality control data, etc.), and a companion document. The Chemistry, Manufacturing, and Controls Documentation (CMC) Electronic Submission Format consists of the CMC ESD and a companion document.

The ESD is a simple text document with a strict markup. It is made up of sections and subsections which define the generic drug to be reviewed/approved by CDER. For example, the Bioavailability/Bioequivalence ESD has a product section where you would explain the product(s) involved, and an ingredient subsection which details the ingredients

[About CDER](#)
[Drug Information](#)
[Regulatory Guidance](#)
[CDER Calendar](#)
[Specific Audiences](#)
[CDER Archives](#)

The Future of Electronic Submissions in OGD
Training will continue to be available at the
University of Maryland, Baltimore County

ESD/EVA Training

ENTRY VALIDATION APPLICATION

Presented By
The Laboratory for Healthcare Informatics
The University of Maryland,
Baltimore County
and
The Office of Generic Drugs
Food & Drug Administration

Instructors

Michele Ritondo, Ph.D.

Industry Consultant
Formerly Lead Developer OGD-UM
Electronic Submission Project

Richard Sponaugle, MS

Senior Systems Engineer,
Elg. Submissions OGD - FDA

Gerald "Kip" Canfield, Ph.D.

Director, Laboratory for Healthcare Informatics
Associate Professor
Information Systems, UMBC

Featuring Additional Speakers from OGD

Under a cooperative agreement with the FDA, UMBC will continue to offer periodic training sessions covering the preparation of electronic ANDAs.

Additional information available at:
<http://lhi5.umbc.edu/fda/>