Transmitting Electronic ISCRs and ICSR Attachments on Physical Media

This document provides specifications for transmitting electronic ICSRs and ICSR attachments on physical media.

I. ADDRESS FOR ELECTRONIC ICSRs AND ICSR ATTACHMENTS ON PHYSICAL MEDIA

Send Physical Media for CDER and CBER to:
Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Rd.
Beltsville, Md. 20705-1266

Attn: (Use one of the attention lines from below)

Attn: AERS ICSR Reports Test

Attn: AERS ICSR Reports Production

Attn: AERS ICSR Reports Attachment Test

Attn: AERS ICSR Reports Attachment Production

Note that the attention line is extremely important because each type of package will be given a different priority for internal delivery depending on the type of report.

II. TYPE OF MEDIA

See the following table:

Type of media	Format	Size
Floppy Disk	3.5 inch 1.44 MB	Up to 14.4 MB (10 disks)
CD ROM	CD-R Joliet Specification	Up to 3 GB (1- 5 CDs)
DVD	DVD-RAM, DVD-Dual Disk DVD-R, DVD-Double Density DVD+R, DVD+/-R	Up to 45 GB (1 to 6 DVDs)
Digital Linear Tape	35/70 or 40/80 DLT tapes using • Veritas backup exec, • Win2000 native backup. Do not use compression.	No limit
Linear Tape Open	LTO 2 (200/400 GB) tapes using • Veritas backup exec • Win2000 native backup Uncompressed.	No limit

III. MEDIA PREPARATION

Send all electronic media adequately secured in a standard binder marked clearly on the outside using one of the headings from below:

ELECTRONIC REGULATORY SUBMISSION FOR ARCHIVE - ICSRs
ELECTRONIC REGULATORY SUBMISSION FOR ARCHIVE – ICSR ATTACHMENTS
ELECTRONIC REGULATORY SUBMISSION FOR ARCHIVE – ICSRs AND ICSR ATTACHMENTS

Additionally, indicate whether the submission contains 15-day Alert reports or 15-day Alert report-followups.[1] The following information should be included on the media labels:

Sponsor, applicant or company name
Name of the product, chemical or ingredient
Appropriate regulatory ID number (e.g., NDA number)
Submission date (dd-mmm-yyyy)
Media series (e.g., “1 of 1”, “1 of 2”)

[1] Current regulations require that postmarketing 15-day Alert reports bear prominent identification as to their contents (i.e., “15-day Alert report,” or “15-day Alert report-followup”).See §§ 310.305(c)(4), 314.80(c)(1)(iv), and 600.80(c)(1)(iv).