Using PDF and SAS Transport for Electronic Submissions

Greg Brolund
CDER / FDA
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Overview

- Why PDF for text
- General PDF recommendations
- SAS Transport for datasets
- General SAS Transport recommendations

Why PDF ?

- Archivable
- De facto standard
- Recommended ICH standard for text submission
- Company commitment to product and future readability

PDF Advantages

- Relatively low cost yet functional in terms of implementation and support.
- Free viewer
- Creation using a PDF device driver or from any Postscript file
- Detailed advance technical agreements are not necessary (as in SGML DTD)

PDF Advantages

- Functional navigational aids
- International support
- Multiple source (Word processor, HTML, SGML, TIFF, others)

General PDF Recommendations

Fonts

- Limit the number of fonts used
- True Type or Adobe Type 1
- Embed all fonts
- Select sub-setting
- Set for 99% to enforce machine names for fonts that may conflict with local font names

Font Info

Fonts In: whitep13.pdf

Original Font	Type	Encoding	Used Font	Type
MSTT31c4d900	Type 1	Custom	Embedded Subset	Type 1
MSTT31c4e600	Type 1	Custom	Embedded Subset	Type 1
MSTT31c4f300	Type 1	Custom	Embedded Subset	Type 1
MSTT31c4fe00	Type 1	Custom	Embedded Subset	Type 1
MSTT31c50900	Type 1	Custom	Embedded Subset	Type 1
MSTT31c51400	Type 1	Custom	Embedded Subset	Type 1

List All Fonts...

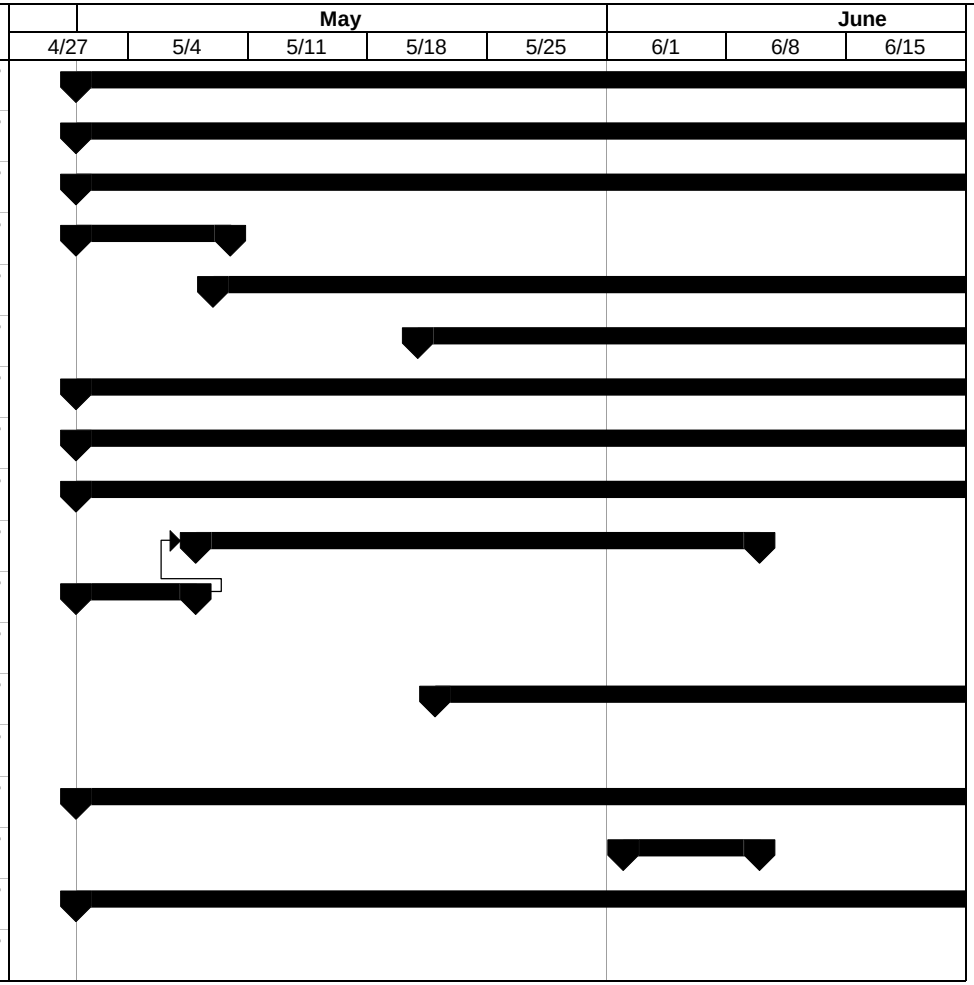
OK

Page Setup

- Present correct orientation
- Page Size 8 1/2 by 11
- Margins to allow binding

DFS 1.3 Schedule

ID	Task Name	Duration	Start	Finish
1	**Deliver Phase 1.3**	99d	5/1/97	9/17/97
2	***Code Enhancements***	87d	5/1/97	8/29/97
3	**Develop Application Standards -V**	74d	5/1/97	8/12/97
6	**Customization**	7d	5/1/97	5/9/97
13	**Search**	63d	5/9/97	8/5/97
19	**Attributes**	61d	5/21/97	8/13/97
26	**Bring into DFS**	63d	5/1/97	7/28/97
37	**Sign Off**	76d	5/1/97	8/14/97
48	**Routing**	77d	5/1/97	8/15/97
56	**Autorender**	23d	5/8/97	6/9/97
64	***Set up Configuration Management***	5d	5/1/97	5/7/97
68	***Install Target***	3d	7/25/97	7/29/97
72	***Develop Test Plan***	62d	5/22/97	8/15/97
77	***Integration Testing***	12d	9/2/97	9/17/97
83	***Training Preparation***	86d	5/1/97	8/29/97
90	***Configure Training Room***	6d	6/2/97	6/9/97
96	***Deliver User Guides***	95d	5/1/97	9/11/97
103	***Deploy Phase 1.3 to Pulmonary***	47d	8/4/97	10/8/97



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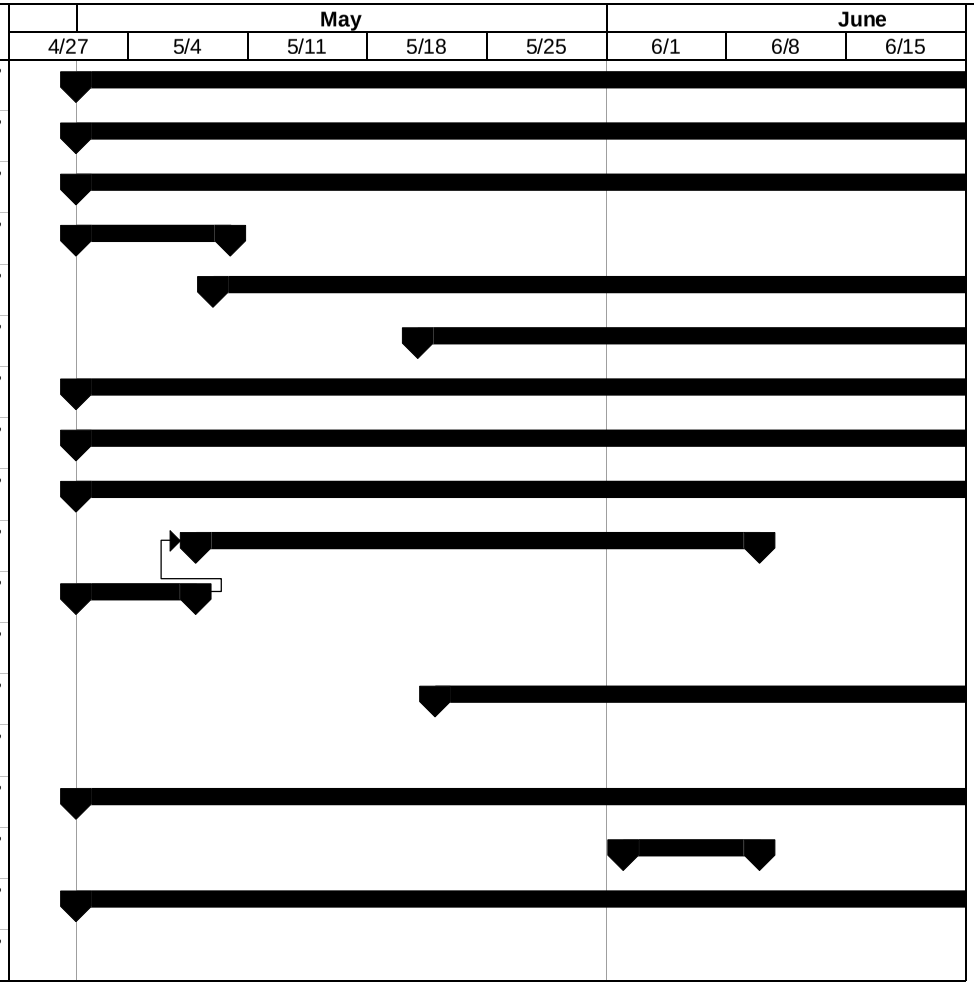


Original Documents

- Use electronic document as the source whenever possible
- Acrobat Distiller recommended

Acrobat Distiller - Job Options

General | Compression | Font Embedding | Advanced

OK

Cancel

Defaults

File Settings

Compatibility: Acrobat 3.0

☐ ASCII Format

Device Settings

Default Resolution: 300 dpi

Default Page Size:

Width: 612 x Height: 792 Points

Acrobat Distiller - Job Options

General | Compression | Font Embedding | Advanced

OK

Cancel

Defaults

☑ Compress text and line art

Color Bitmap Images

☑ Downsample to 300 dpi

☑ Automatic Compression: ZIP/JPEG Medium

☐ Manual Compression: JPEG Medium

Grayscale Bitmap Images

☑ Downsample to 300 dpi

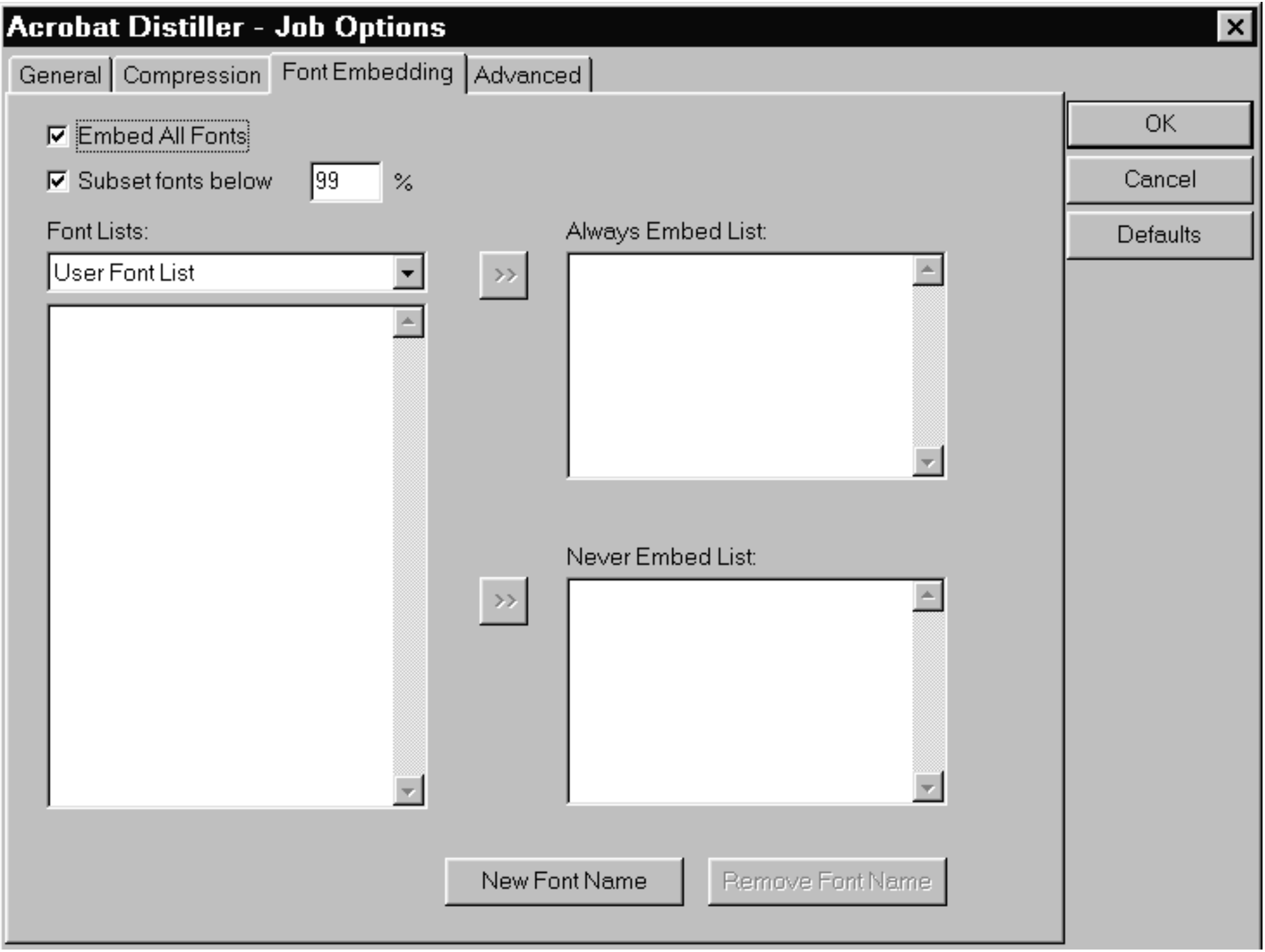
☑ Automatic Compression: ZIP/JPEG Medium

☐ Manual Compression: JPEG Medium

Monochrome Bitmap Images

☑ Downsample to 300 dpi

☑ Manual Compression: ZIP


Acrobat Distiller - Job Options
General
Compression
Font Embedding
Advanced
Embed All Fonts
Subset fonts below
99
%
Font Lists:
User Font List
Always Embed List:
Never Embed List:
New Font Name
Remove Font Name
OK
Cancel
Defaults

Acrobat Distiller - Job Options

General | Compression | Font Embedding | Advanced

- [ ] Distill with prologue.ps / epilogue.ps
- [x] Convert CMYK Images to RGB
- [ ] Preserve OPI Comments
- [ ] Preserve Overprint Settings
- [ ] Preserve Halftone Screen Information

Apply — Transfer Functions

Remove — Under Color Removal / Black Generation

Color Conversion

- ( ) Unchanged
- (•) Device Independent (More Accurate)
- ( ) Device Dependent (Faster Display)

OK

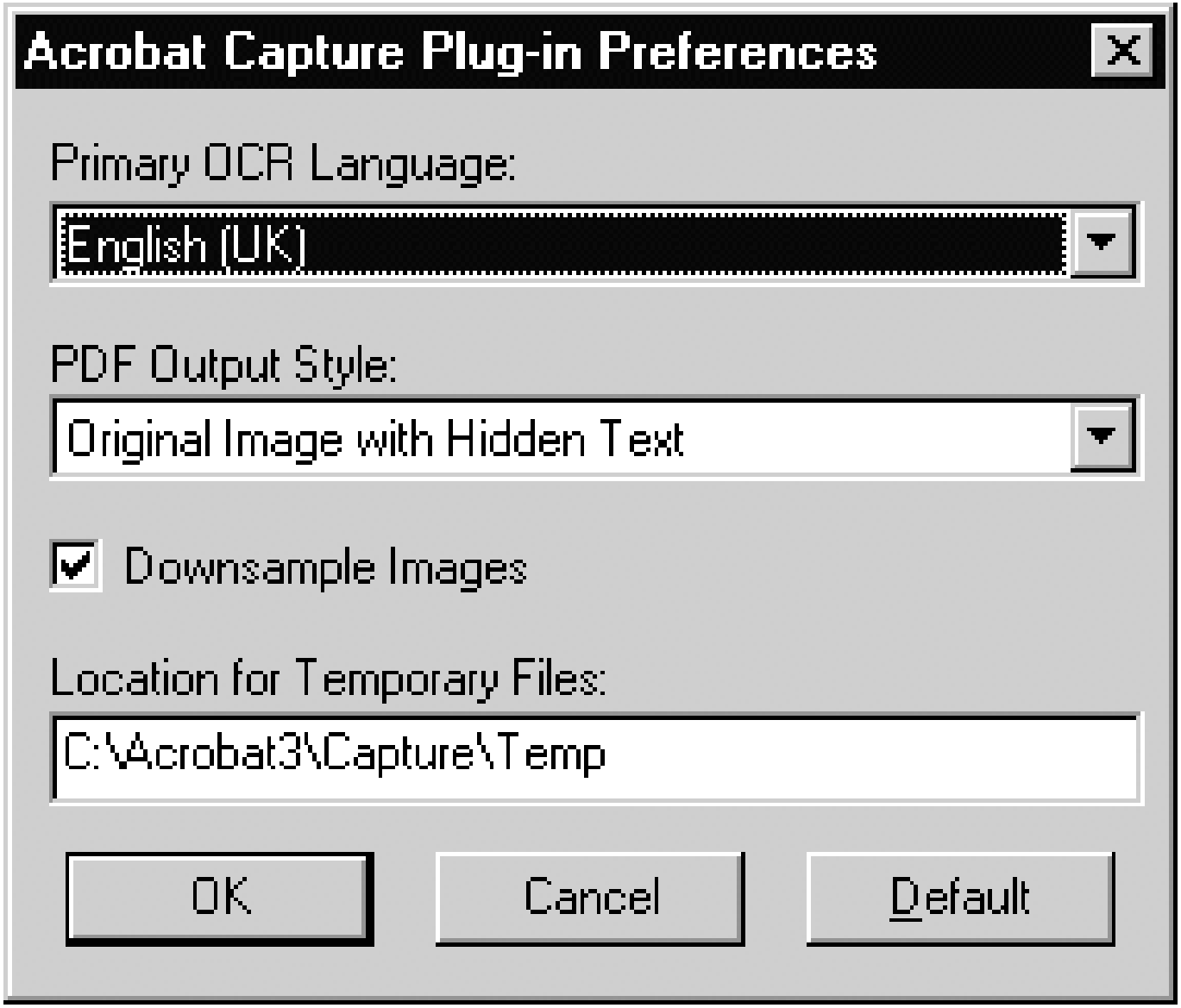
Cancel

Defaults

Paper Documents

- Legibility is the primary consideration - select appropriate scanning resolution
- Black and white, if possible, to minimize size
- 8 bit gray scale or 24 bit RGB if necessary
- Capture options - if OCR is chosen
  - Image + hidden text

Capture Options



Hyperlinks and Bookmarks

- In general:
  - Bookmarks as a table of contents
  - Hyperlinks for off page references
- See specific subsections for recommendations
- Select “Inherit Zoom” when creating links

Document Information Fields

- Provide index to make the fields searchable
- Use title field for requested information
- See guidance for specific information for each NDA item

General Info

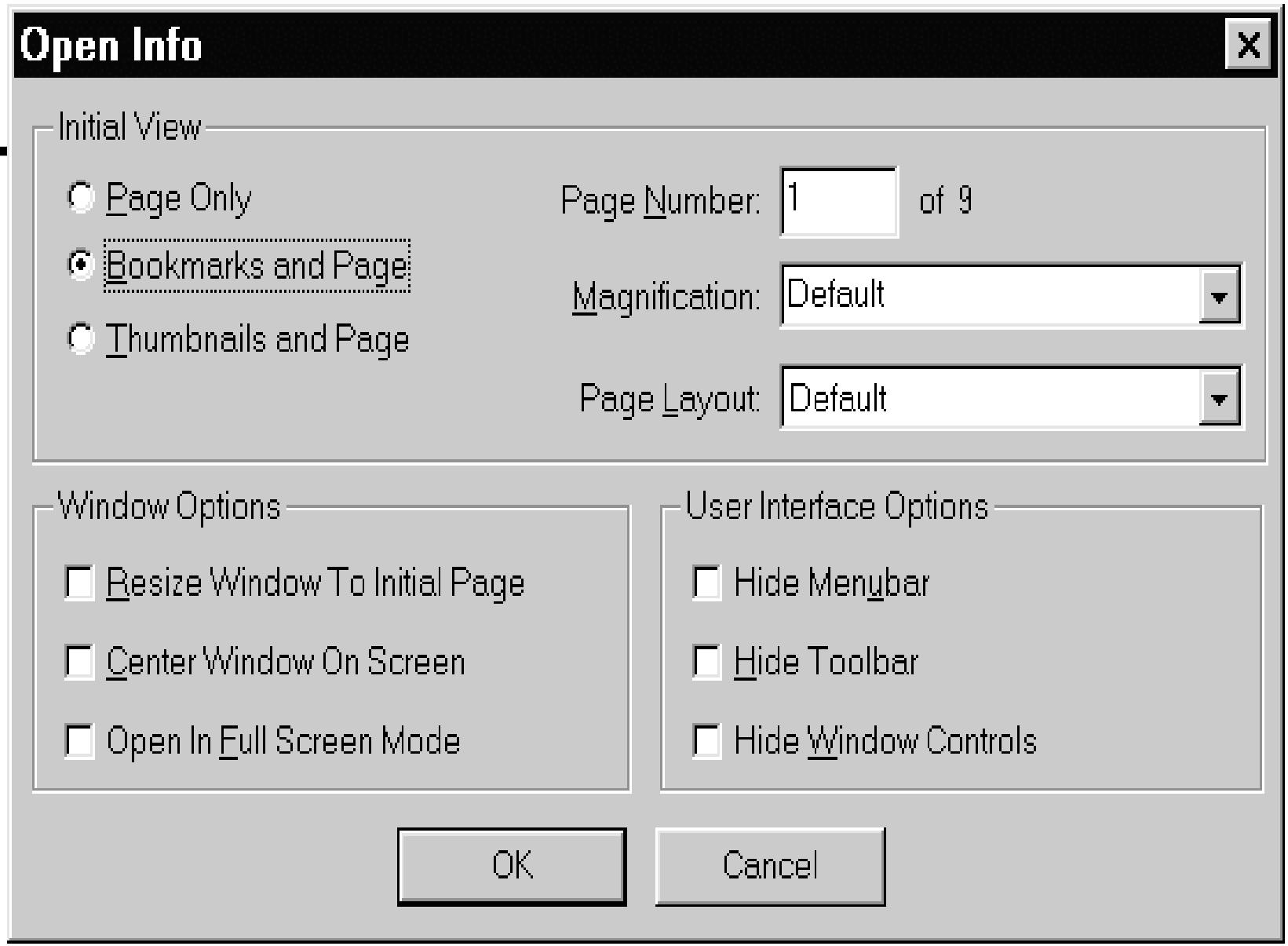
D:\ichm2\Acknowledgment message\whitep13.pdf

Title:	N123456, package insert, approved, 10jan1
Subject:	
Author:	
Keywords:	
Creator:	PSCRIPT.DRV Version 4.0
Producer:	Acrobat Distiller 3.01 for Windows
Created:	4/17/98 8:50:11 AM
Modified:	4/17/98 8:50:11 AM
Optimized:	No
File Size (Bytes):	77175

OK Cancel

Open Dialog Box

- Initial view -> Bookmarks & Page
- Magnification and Page Layout to default


Open Info
Initial View
Page Only
Bookmarks and Page
Thumbnails and Page
Page Number:
1
of 9
Magnification:
Default
Page Layout:
Default
Window Options
Resize Window To Initial Page
Center Window On Screen
Open In Full Screen Mode
User Interface Options
Hide Menubar
Hide Toolbar
Hide Window Controls
OK
Cancel

Naming PDF Files

- No long file names at this time
- report12.PDF
- See specific subsections for additional naming recommendations

Security

- Do not restrict access

Document Security

Security Method:	None
Open Password:	No
Security Password:	No
Printing:	Allowed
Changing the Document:	Allowed
Selecting Text and Graphics:	Allowed
Adding or Changing Notes and Form Fields:	Allowed

OK

Indexing

- Acrobat Catalog
- Subdirectory for indexes
- See subsections for additional recommendations

SAS Transport for Datasets

- Open specification
  - www.sas.com/techsup/download/technote/ts140.txt
- Compatible with commonly used spreadsheet and statistical software
- Can be transferred to common database systems
- Easy to use in CDER and in many companies
- Third part software to build and read SAS Transport files

SAS Transport Recommendations

- SAS Transport Version 5
- Provide data definitions as PDF documents
  - Provide descriptive information in the transport description field
- Submit example data prior to filing
- Guidance has specific recommendations for each appropriate NDA items

SAS Transport

- 8 character file names
- 25 Mbyte files (or less)
- Place files in the NDA item “dataset” folder