CUSTOMER SPOTLIGHT

# Adobe® Acrobat® Food and Drug Administration

**Drug approvals are more efficient when new drug applications are submitted as searchable PDF files**

**KEY BENEFITS:**

- PDF files can speed NDA review processes because reviewers can access documents online instead of waiting for paper documents to be delivered.
- Faster review of NDAs in PDF brings critical medications to market sooner and helps drug companies recoup as much as $1 million a day in product development costs.
- Acrobat automatically converts Microsoft Word for Windows® styles to bookmarks, reducing the time and cost to drug companies of preparing easily navigable electronic NDAs.
- Acrobat speeds creation of review documents because reviewers can copy drug companies' tables and graphs from PDF files into Microsoft Word for Windows files.
- The Document Compare feature in Acrobat allows the staff to view multiple versions of an NDA file side-by-side, summarize notes, and sort by date or author.
- Submitting PDF files instead of paper documents saves pharmaceutical companies the expense of submitting paper documents containing tens of thousands of pages.
- Receiving NDAs as PDF files instead of paper copies alleviates storage costs.

When timely approval of a drug can enhance the quality of life, a technology that accelerates the approval process can literally become a lifesaver. Each year, the Food and Drug Administration (FDA) receives many submissions, including more than 100 original new drug applications (NDAs) from pharmaceutical companies that want to introduce new drugs, market a drug for a different therapeutic purpose, or change dosage recommendations. The FDA can now review NDAs more efficiently and at a lower cost with Adobe Acrobat software and PDF. Everyone wins: the consumers who benefit from faster introduction of critical medications, the drug companies that can earn as much as $1 million a day from leading drugs, and the taxpayers who fund a more efficient agency.

The FDA employs 700 reviewers to review NDAs, which can contain as many as 1,000 volumes of 300 pages each and must be submitted in triplicate. "When NDAs are submitted in PDF instead of on paper, reviewers have fully searchable electronic files that are easier to locate and distribute. Plus, the costs to the agency of storing these documents are reduced substantially," says Greg Brolund, associate director for technology and policy for the FDA's Center for Drug Evaluation and Research (CDER). "And with features in Acrobat, including rich annotation tools and the ability to copy charts from PDF files on a PC to Microsoft Word or Microsoft Excel or compare versions of PDF files side by side, PDF can help accelerate the decision to approve or not approve an NDA."

**"Pharmaceutical companies may find it an economic advantage to submit NDAs electronically. In some cases, they can eliminate days or weeks printing and validating nearly a million pages and reduce photocopying and shipping costs substantially. What's more, leading drugs can earn $1 million a day—receiving approval to introduce a new drug even several days earlier impacts the bottom line."**

***—Greg Brolund***
***Associate Director for Technology and Policy***

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## REDUCED STORAGE AND COURIER COSTS

Since 1997 when the FDA first allowed pharmaceutical companies to submit NDAs in PDF, the agency has received more than 80 such submissions containing the equivalent of more than 7 million printed pages. "Pharmaceutical companies may find it an economic advantage to submit NDAs electronically," says Brolund. "In some cases, they can eliminate days or weeks printing and validating nearly a million pages and reduce photocopying and shipping costs substantially. What's more, leading drugs can earn $1 million a day—receiving approval to introduce a new drug even several days earlier impacts the bottom line."

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***—Greg Brolund***
***Associate Director for Technology and Policy***

For the FDA, the most noticeable benefits of PDF files are a dramatic reduction in storage space and greater efficiency for reviewers. A single NDA can contain hundreds of thousands of pages, and reviewers often work on as many as five NDAs at a time. The FDA stores paper-based NDAs in multiple document rooms across its campus. When reviewers have questions about specific studies, they have to request that a paper-copy volume be pulled from a document room. Obtaining a single file can take a day or more—and reviewers might easily request dozens of files during the course of a review.

In contrast, NDAs submitted in PDF are stored on a central server so that reviewers can access them instantly via the corporate server or intranet. "By enabling staff to immediately find answers to questions, PDF speeds review," says Brolund.

## GUIDELINES FOR SEARCHABILITY

To take full advantage of the electronic format, the FDA provides guidance for submitting NDAs as PDF files. For example, the PDF files should include bookmarks and hypertext links to table of contents entries. "Acrobat automates this process for documents created with Microsoft Word, reducing the cost of document preparation," says Brolund. When drug companies use Acrobat to create PDF files, Word styles—for example, for table of contents and section titles—are automatically converted to bookmarks in the PDF file. The guidance also stipulates that document information fields contain specific information so reviewers can search NDAs for particular information. The Catalog feature of Acrobat also enables full text searches across multiple documents. "When reviewers can quickly find the information they need, we improve our service and our effectiveness as a government agency," says Brolund.

## STREAMLINED APPROVAL PROCESS

Reviewers also take advantage of Acrobat when writing an NDA review, which recommends whether applications should be approved. The NDA review documents are created in Microsoft Word, often by pulling information directly from NDAs. Once a review document is completed, it is output in a single step from Microsoft Word to PDF.

The Document Compare feature in Acrobat for Windows allows reviewers to confirm changes by opening two versions of a PDF file in tiled windows for automatic, side-by-side, onscreen comparison. Using the same feature, they can also summarize notes and sort by date and author.

The FDA is evaluating the SelfSign digital signature feature in Acrobat for review of summary documents. "The security features in Acrobat could be used to add another level of security and data integrity to the review process," says Brolund.

## LEVERAGING BENEFITS OVER TIME

Over the life of a drug, a manufacturer might submit several changes, such as different dosages or therapeutic applications. "Finding documents online is much easier than sifting through millions of pages of paper," says Brolund.

"Acrobat improves our service by helping to make the review of NDAs more efficient," concludes Brolund. "By automatically converting Microsoft Word styles to hyperlinks and bookmarks, it helps drug companies create PDF files that reviewers can more quickly navigate. And it speeds the creation of NDA review documents."

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