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FDA Withdraws Older Guidances in Move Toward Advancing eCTD

The Center for Drug Evaluation and Research’s (CDER) recent move to withdraw three old electronic submission guidances is just another important step in the agency’s avowed policy of advancing the electronic common technical document (eCTD) format, says Nancy Smerkanich, vice president of regulatory affairs at Octagon.

The agency announced Sept. 28 that it was withdrawing the three guidances because they “are no longer consistent with more recent guidances and no longer reflect the agency’s preferred format for receiving electronic submissions.”

Smerkanich said that while the agency is recommending that sponsors submit in eCTD format, an internationally agreed upon format, many sponsors are not prepared to support the format with cur-

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Electronic Data Breach Ramifications Can Damage Operations, Reputation

With more than 55 million Americans identified as edata breach victims, 2005 may go down in history as the “Year of the Breach,” said health industry privacy attorney Renee Martin at the Thirteenth Annual HIPAA Summit in Washington, D.C., Sept. 26.

The repercussions for FDA-regulated companies are serious, she said. In addition to running afoul of stiff federal regulations like the Health Insurance Portability and Accountability Act (HIPAA) and 21 CFR Part 11, data breaches can lead to nasty and expensive class action suits, tort claims and contractual damages situations, Martin said.

But some companies don’t realize that while HIPAA does not force companies to publicly disclose edata breaches, state laws in

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rent processes and technologies and many more are not comfortable with their organizations' understanding of the eCTD format.

The withdrawal itself and the FDA's statement were applauded by Smerkanich, who said that as more companies become comfortable with using the eCTD format, its popularity will grow.

Among other benefits, she said eCTDs can be a significant help to FDA-regulated life sciences companies during life cycle management, especially those involved with investigational new drugs (INDs). "They won't have to resubmit data over and over again anymore," she told *PIR* Oct. 5.

Citing the eCTD format as "preferred by the FDA because it is more efficient than other choices and consistent with FDA's technical capabilities," the agency withdrew the following submission guidances:

- Providing Submissions in Electronic Format — New Drug Applications (NDAs);
- Providing Regulatory Submissions in Electronic Format — Abbreviated New Drug Applications (ANDAs); and
- Providing Regulatory Submissions in Electronic Format: Annual Reports for NDAs and ANDAs.

Effective Dec. 31, 2007, all references to these guidances will be removed from the electronic submissions docket, the FDA said.

Octagon has assisted organizations in implementing the eCTD submission format, Smerkanich said. The company provides training and supporting services and technologies to help companies transition into eCTD format.

She advised companies exploring eCTDs to make certain to engage all company business units in the project. "Regulatory affairs and all other function areas must understand [eCTDs] and get involved," she said.

Octagon is currently working with several "relatively small" FDA-regulated life sciences companies on eCTD projects; four are INDs and two are marketing-related.

For nearly a decade, the FDA has been "working to expand its ability to receive and review marketing applications electronically," the agency said in the September guidance withdrawal statement.

In 1999, the agency issued two guidances and one draft guidance that made recommendations to applicants who wanted to submit applications to the agency electronically. In general, those guidances recommended submitting documents as PDFs, electronic data/case report tabulations as SAS transport files, and the NDA table of contents as a PDF.

But the agency later adopted the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) CTD headings and subheadings for marketing applications. The ICH then issued specifications for the electronic version of the CTD.

Last October, the agency issued the guidance "Providing Regulatory Submissions in Electronic Format — Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications."

That guidance differs from the 1999 guidances by saying that the application table of contents does not need to be submitted as a PDF file. Instead, it is to be submitted as an XML (extensible markup language) file.

XML has "numerous advantages" over the older PDF format, the agency noted. The "most significant of which is the ability to update the application table of contents automatically as new amendments are received."

The eCTD format gives sponsors and reviewers access to real-time, up-to-date cumula-

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tive table of contents information that provides easy and immediate access to all files included in an application, regardless of when they were included, or in what submission they are located, the FDA noted.

Despite the FDA's nudge toward the eCTD format, Smerkanich notes that the agency is making a point of still accepting other formats. "They still take paper," she pointed out.

Applicants now have three choices when submitting a marketing application electronically:

- Use the eNDA/eANDA format;
- Use the eCTD format; or
- Use a "hybrid" submission (the older eNDA format with the table of contents organized using the newer CTD headings).

While noting that the agency still receives submissions that are a combination of paper and electronic formats, the FDA pointed out that this option wouldn't be suitable for sponsors using the eCTD format. That's because it would negate the intent of having all portions of the application readily available for review via the XML table of contents.

Smerkanich said she was "a little disappointed" that the Center for Biologics Evaluation and Research (CBER) was not formally included in the guidance withdrawal.

Although CBER supports and encourages the use of the eCTD format, the center also said it recognizes that in certain situations a sponsor may not be capable of providing submissions in eCTD.

In that case, CBER recommends sponsors consult industry guidance titled "Providing Regulatory Submissions to the Center for Biologics Evaluation and Research in Electronic Format — Biologics Marketing Applications, Product License Application/Establishment License Application and New Drug Application," which is available online at www.fda.gov/cber/gdlns/ebla.pdf. — Michael Causey

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