

FDA NEWS RELEASE

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FDA launches website to help regulated industries save time, resources
New FDA report contains 19 action items to improve transparency to companies

The U.S. Food and Drug Administration today introduced a new Web resource called FDA Basics for Industry (www.fda.gov/FDABasicsforIndustry) to help companies and others save time and resources in their interactions with the agency.

The website includes basic information about the regulatory process, including information that is frequently requested by industry.

"Clarity and consistency are pillars of an effective regulatory system that efficiently regulates products essential to health," said FDA Commissioner Margaret Hamburg, M.D. "In order to succeed, the FDA must clearly communicate standards and expectations to the industries it regulates."

Part of the agency's ongoing transparency initiative, the site is one of the 19 action items contained in a 46-page report titled "FDA Transparency Initiative: Improving Transparency to Regulated Industry." Other action items include:

setting an agency-wide expectation that e-mail questions to the FDA involving the regulatory process will, whenever possible, receive an answer within five business days, or a response stating when an answer can be expected

making agency presentations at key meetings widely available

developing and executing a project to promote uniform processes and procedures across field districts.

The entire list of action items contained in the report is available [here](#).

(<http://www.fda.gov/AboutFDA/Transparency/TransparencytoRegulatedIndustry/PhaseIIITransparencyReport/ActionItemsandDraftProposalsbyTopicArea/default.htm>)

"We have heard from small and large companies about the need for the FDA to more clearly communicate about its standards and expectations – both for regulated products generally and for specific applications," said Principal Deputy Commissioner Joshua Sharfstein, M.D., chairman of the agency's Transparency Task Force.

The report also contains five draft proposals to improve FDA's transparency to regulated industry. The draft proposals, available for public comment for 60 days, include publishing a timeline on the FDA website for high priority guidance documents in development. The FDA would disclose dates

for publication of the draft guidance, receipt of public comments, and publication of the final guidance.

Commissioner Hamburg launched the FDA's Transparency Initiative in June 2009 in response to President Obama's commitment to openness in government and steps taken by the U.S. Department of Health and Human Services to make transparency a priority.

Since that time, the FDA has created a new Web page titled FDA Basics that features questions, answers, videos, and other materials describing how the FDA works to protect and promote public health. The page has been viewed by more than 900,000 people worldwide.

The agency also has established an online performance program for FDA offices nationwide. Called FDA-TRACK, the program features monthly metrics for more than 100 agency offices and provides insight for the public into the FDA's decision-making and regulatory activities.

For more information:

FDA Basics for Industry

<http://www.fda.gov/FDABasicsforIndustry>

FDA Transparency Initiative: Improving Transparency to Regulated Industry – Report

<http://www.fda.gov/AboutFDA/Transparency/TransparencytoRegulatedIndustry/PhaseIIITransparencyReport/default.htm>

FDA Transparency Initiative: Improving Transparency to Regulated Industry – Executive Summary

<http://www.fda.gov/AboutFDA/Transparency/TransparencytoRegulatedIndustry/PhaseIIITransparencyReport/ExecutiveSummary/default.htm>

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