Morgan Lewis

alert

FDA and healthcare lawflash

www.morganlewis.com

FDA's Transparency Proposals Would Disclose Product Applications and Significant Information on Status and Content

May 28, 2010

As part of President Obama's Open Government Initiative, the U.S. Food and Drug Administration (FDA or the Agency) launched its own Transparency Initiative in June 2009. FDA commissioner Dr. Margaret Hamburg created and charged an internal task force to develop recommendations that would help explain how the FDA operates and makes key decisions. On May 19, 2010, this Transparency Task Force released a report containing 21 draft proposals that would significantly expand the disclosure of industry information by the FDA. The report states that "[the] proposals reflect a careful balancing of the importance of transparency with the importance of protecting trade secrets and confidentiality." Dr. Joshua Sharfstein, principal deputy commissioner of the FDA and chair of the Transparency Task Force, has requested input "on whether we have struck the right balance between disclosure and confidentiality in support of public health."

FDA's draft proposals cover a broad array of the Agency's actions, including both premarket decision-making and postmarket enforcement and related activities. This LawFlash focuses on the 10 proposals that would disclose information relating to product applications for drugs, biologics, and medical devices. Morgan Lewis is concurrently issuing a companion LawFlash that discusses FDA's other transparency proposals, addressing FDA and DOJ enforcement priorities and actions, import evaluations, inspectional results, recalls, and Warning Letters and untitled letters.

Proposals Relating to Premarketing and Marketing Applications: Is There an Appropriate Balance Between Disclosure and Confidentiality?

A primary goal of the Transparency Initiative, as described by FDA officials, is to better explain the FDA's actions. The Transparency Task Force took a broad approach to achieving this objective; its report describes three phases: FDA Basics, which provides information for the public on FDA and how it works; FDA's Public Disclosure Policy; and Transparency to Regulated Industry. This FDA report containing 21 proposals addressed only the second phase of the transparency initiative. Thus, these proposals are not intended to make recommendations for greater transparency to regulated industry, but rather, to provide for greater disclosure of information to the public.

In developing its proposals, the FDA adopted its own definition of "trade secret" and used this definition in deciding which information could be disclosed. The Transparency Task Force believes that trade secrets should remain confidential, and that such information should be redacted before documents are

disclosed. The Transparency Task Force also considered information that is currently withheld from disclosure on the basis that it is "confidential commercial information." Significantly, the Task Force made a determination that some information previously treated as "confidential commercial information" need not be protected from disclosure, notwithstanding protection of such information under the Freedom of Information Act (FOIA) and existing FDA regulations. The report states only that "[c]hanges to statutes or regulations may be needed to implement some of the proposals." As the legality of FDA's release of trade secrets and confidential information could potentially violate the FOIA statute and/or the U.S. criminal code relating to protection of trade secrets (18 U.S.C. § 1839), it is likely these recommendations will be closely vetted and potentially legally challenged if they move forward.

Currently, FDA generally does not disclose any information about the existence, status, or contents of an investigational drug or device application submitted to the Agency, until the product has been approved, licensed, or cleared. Statutes and FDA regulations generally prohibit the release of information from or about an unapproved application. Nonetheless, the Transparency Task Force has proposed to disclose to the public information currently considered confidential information that has been submitted to FDA in such applications.

Specific Proposals Addressing Premarket Decision-Making

The draft proposals include 10 regarding disclosing information about drugs (human and animal), biologics, or medical devices under review by the Agency. These draft proposals, if implemented, will have a profound effect on the ways companies disclose information about their development pipelines to the general public and stakeholders, including investors. It will also affect how companies conduct due diligence of potential product or company acquisition targets or collaboration partners. Provided below is a brief summary of the specific proposals on product applications, including investigational applications:

1. **Existence or Nonexistence of Investigational Applications.** FDA is proposing to disclose the existence and, when asked, confirm the existence or nonexistence of investigational human and animal drug and device applications. FDA is also proposing that for investigational applications, the disclosure should include the name of the application sponsor, the date the application was received, the proposed indication(s) or intended use(s) of the product, and the proposed proper and/or trade name of the product, if available.

2. **Clinical Trials: Holds, Withdrawals, and Terminations.** FDA is proposing to disclose (1) whether an investigational new drug (IND) application has been placed on hold, terminated, or withdrawn; whether an investigational device exemption (IDE) has been terminated or withdrawn; or whether an investigational exemption for a new animal drug has been terminated, and (2) if an IND has previously been placed on hold, whether and when the hold is lifted. FDA is also proposing that a statement that such actions may be taken for various reasons, only some of which relate to safety or effectiveness, be included in a disclosure.

3. **Existence or Nonexistence of Marketing Applications.** FDA is proposing to disclose the fact that an NDA, NADA, ANDA, or ANADA, or a BLA, PMA, or 510(k) application or supplement was submitted (or resubmitted) to the Agency at the time the application is received by FDA. FDA is also proposing that the disclosure should include the name of the application sponsor, the date the application was received, the proposed indications or

intended use of the product, and the proposed proper and/or trade name of the product, if available.

4. **Withdrawn or Abandoned Unapproved Applications.** FDA is proposing to disclose that an unapproved NDA, ANDA, NADA, ANADA, BLA, PMA, or uncleared 510(k) has been withdrawn or, if FDA determines that the application was abandoned, abandoned by the sponsor. If the drug, biological product, or device is associated with a significant safety concern, FDA is proposing to include in a disclosure a brief description of the product, the use for which approval was sought or obtained, and the identified safety concern.

5. **Withdrawn or Abandoned Application for a Designated but Unapproved Orphan Drug or Designated Minor Use/Minor Species Animal Drug, Not Due to Safety Concerns.** When an application for a designated orphan drug or a designated minor use/minor species animal drug has been withdrawn, terminated, or abandoned, FDA intends to disclose, if it determines, based on its review, that the application was not withdrawn, terminated, or abandoned for safety reasons and the product, if approved, could represent a significant therapeutic advance for a rare disease or for a minor animal species. FDA is also proposing that a disclaimer, which provides that FDA's expressed views about the product do not reflect whether a subsequent application involving the product will be accepted for filing or will be approved by FDA, accompany the disclosure of this information.

6. **Letters Issued When FDA Does Not Accept a Marketing Application or Approve or Clear a Marketing Application.** FDA is proposing to disclose the fact that the Agency has issued a refuse-to-file or complete response letter in response to an original NDA, BLA, or an efficacy supplement for an NDA or BLA at the time the refuse-to-file or complete response letter is issued, and at the same time, disclose the refuse-to-file or complete response letter, which contains the reasons for issuing the letter.

   In addition, FDA is proposing to disclose the fact that the Agency has issued a refuse-to-approve letter in response to a NADA, or a supplemental NADA to add a new species or indication, at the time the refuse-to-approve letter is issued, and should, at the same time, disclose the refuse to approve letter, which contains the reasons for issuing the letter.

   FDA is also proposing to disclose the fact that the Agency has issued a "not approvable" letter in response to a PMA for a medical device and the fact that FDA has issued an "additional information (AI)" letter in response to a 510(k) submission, and should, at the same time, disclose the reasons for issuing the "not approvable" letter or "additional information (AI)" letter, which contains the reasons for issuing the letter.

7. **Safety and Effectiveness Data.** FDA is proposing to disclose relevant summary safety and effectiveness information from an investigational application, or from a pending marketing application, if the Agency concludes that disclosure is in the interest of the public health, which includes when FDA believes it is necessary to correct misleading information about the product that is the subject of the application.

   In addition, FDA is proposing to convene a group of internal and external stakeholders to discuss the possible uses of nonsummary safety and effectiveness data from product applications, the circumstances under which it would be appropriate for sponsors to disclose

nonsummary safety and effectiveness data from applications submitted to FDA, and if appropriate, the format and the method by which disclosure should occur.

FDA is seeking comments on all of the above proposals, as well as on how to prioritize the proposals before July 20, 2010. For additional information, or assistance in preparation of comments, please contact any of the following attorneys in our FDA and Healthcare Practice:

Washington, D.C.

Kathleen M. Sanzo	202.739.5209	ksanzo@morganlewis.com
M. Elizabeth Bierman	202.739.5206	mebierman@morganlewis.com
Stephen Paul Mahinka	202.739.5205	smahinka@morganlewis.com
Dr. Phoebe Mounts	202.739.5898	pmounts@morganlewis.com

About Morgan, Lewis & Bockius LLP

With 22 offices in the United States, Europe, and Asia, Morgan Lewis provides comprehensive transactional, litigation, labor and employment, regulatory, and intellectual property legal services to clients of all sizes—from global Fortune 100 companies to just-conceived startups—across all major industries. Our international team of attorneys, patent agents, employee benefits advisors, regulatory scientists, and other specialists—more than 3,000 professionals total—serves clients from locations in Beijing, Boston, Brussels, Chicago, Dallas, Frankfurt, Harrisburg, Houston, Irvine, London, Los Angeles, Miami, Minneapolis, New York, Palo Alto, Paris, Philadelphia, Pittsburgh, Princeton, San Francisco, Tokyo, and Washington, D.C. For more information about Morgan Lewis or its practices, please visit us online at www.morganlewis.com.

This LawFlash is provided as a general informational service to clients and friends of Morgan, Lewis & Bockius LLP. It should not be construed as, and does not constitute, legal advice on any specific matter, nor does this message create an attorney-client relationship. These materials may be considered **Attorney Advertising** in some states. Please note that the prior results discussed in the material do not guarantee similar outcomes.

© 2010 Morgan, Lewis & Bockius LLP. All Rights Reserved.