

## BioRegulation

# The Potential Impact of the FDA's Issuance of a "Complete Response Letter" on Publicly-Traded Life Sciences Companies

David A. Kotler and Jennie B. Krasner

### ABSTRACT

Effective August 11, 2008, the Food and Drug Administration ("FDA") will issue a "complete response letter" ("CRL") when it does not approve a new drug application ("NDA") instead of the "approvable" and "not approvable" letters that it formerly issued in that circumstance.<sup>1</sup> This new rule will impact publicly-traded life sciences companies and their directors and officers—who already are squarely in the crosshairs of the plaintiffs' securities bar<sup>2</sup>—because such companies will need to carefully consider whether the information they disclose upon receiving a CRL could be "materially misleading" under the federal securities laws.

### SUMMARY OF THE NEW RULE

The FDA first proposed the CRL approach in July 2004 "to adopt a consistent and more neutral mechanism to convey that [the FDA] cannot approve a drug marketing application in its current form."<sup>3</sup> According to the FDA, the new rule is intended to address two related deficiencies with the prior protocol.

First, the new rule is intended to address the "somewhat blurred" distinction between the "approvable" and "not approvable" letters that the FDA had issued when it denies an

NDA.<sup>4</sup> The "approvable" letter was originally meant to indicate that the FDA would potentially approve a drug if the applicant made some changes to its application and/or supplied some limited additional information, while the "not approvable" letter was meant to indicate that there were major deficiencies with the application that prevented approval.

Second, the new rule is meant to address concerns that drug manufacturers had expressed to the FDA "that a not-approvable letter sent an unintended message that a marketing application would never be approved, which could adversely

affect a company's ability to raise capital."<sup>5</sup>

The new rule, which took effect on August 11, 2008, provides that the FDA will issue a CRL any time that it determines it "will not approve an NDA ... in its present form for one or more reasons."<sup>6</sup> According to the FDA, a CRL will "usually" detail all of the deficiencies with the application.<sup>7</sup> The FDA has used this same procedure for Biologics License Applications since 1998.

### POTENTIAL IMPACT ON PUBLICLY-TRADED LIFE SCIENCES COMPANIES

Federal securities laws prohibit publicly-traded companies from disclosing materially misleading information to the investing public. The materiality threshold is generally determined by considering whether a reasonable investor would view the information as altering the "total mix" of information available. Under the new regulations, a publicly-traded life sciences company will need to be vigilant in ensuring that its disclosure of the receipt of a CRL from the FDA is accompanied by actual specific information contained in the CRL to avoid an accusation that its disclosure is materially misleading.

The former regulations prohibited the FDA from publicly acknowledging the existence of an NDA before it sent an "approvable" letter to the applicant;<sup>8</sup> the FDA also usually did not disclose its correspondence with the applicant with respect to an NDA's approval status unless it had approved the NDA.<sup>9</sup> The company applying for the NDA, however, was not only permitted to publicly disclose information regarding its NDA,

COPYRIGHT © 2008 BY  
THE JOURNAL OF BIOLAW & BUSINESS



WWW.BIOLAWBUSINESS.COM

David A. Kotler is a partner in Dechert's White Collar and Securities Litigation group. Mr. Kotler advises and represents life sciences and other clients in a wide range of complex corporate and commercial litigation matters involving the financial markets, contracts and business torts. Mr. Kotler was recently named as one of the top "40 under 40" by the New Jersey Law Journal.

Jennie B. Krasner is an associate in Dechert's White Collar and Securities Litigation group.

Cite as: David A. Kotler and Jennie B. Krasner, *International Trade Commission*. J. BIOLAW & BUS., Vol. 11, No. 4, 2008.

including its correspondence with the FDA (even if it had not received approval for the drug or an “approvable” letter), but often would choose to do so. Thus, if a company did disclose that it had received an “approvable” or “not approvable” letter from the FDA in response to its NDA, investors could assess the likelihood of the drug’s eventual approval, even if the company supplied little additional information regarding the drug’s potential for approval.

The new CRL regime prohibits the FDA from publicizing the existence of an NDA until it approves the NDA, and is also expected to continue the FDA’s prior practice of keeping its NDA correspondence with the applicant private unless it has approved the NDA.<sup>10</sup>

“Effective August 11, 2008, the Food and Drug Administration (“FDA”) will issue a “complete response letter” (“CRL”) when it does not approve a new drug application (“NDA”) instead of the “approvable” and “not approvable” letters that it currently issues in that circumstance.”

Furthermore, the new regime abolishes the “approvable” and “not approvable” letters, substituting the CRL in any instance where the FDA does not approve the NDA. Thus, if the applicant discloses that it has received a CRL from the FDA, without additional information, an investor possesses even less information with respect to the drug’s potential approvability than under the old regime where a company would disclose that it had received an “approvable” or “not approvable” letter. Therefore, to avoid possible claims of securities fraud arising out of its disclosure following receipt of a CRL, this new rule could require publicly-traded life sciences companies to disclose specific information contained in a CRL to the investing public. 

#### ENDNOTES

1. Final Rule, 73 Fed. Reg. 39588 (July 10, 2008). In addition to the CRL mechanism described above, the new rules also revise regulations concerning extension of the review cycle, starting a new cycle under certain circumstances, and abbreviated new drug application response procedures.
2. See Dechert Survey of Securities Fraud Class Actions Brought Against Life Sciences Companies, available at [www.dechert.com/library/Survey\\_of\\_Securities\\_Fraud\\_CA\\_06-08.pdf](http://www.dechert.com/library/Survey_of_Securities_Fraud_CA_06-08.pdf).
3. Applications for Approval to Market a New Drug; Complete Response Letter; Amendments to Unapproved Applications, 69 Fed. Reg. 43351 (proposed July 9, 2004) (to be codified at 21 C.F.R. pts. 312, 314, 600 and 601).
4. *Id.* at 43352. See also 21 C.F.R. § 314.110 (“approvable” letter) and § 314.120 (“not approvable” letter).
5. Final Rule, 73 Fed. Reg. at 39606 § IV(A)(1).
6. 73 Fed. Reg. at 39589 § II.
7. *Id.*
8. See 21 C.F.R. § 314.430(b), (c). If a company publicly acknowledged that it had a pending NDA prior to receiving an “approvable” letter, the FDA could discretionarily choose to disclose only certain summary information “appropriate for public consideration of a specific pending issue.” *Id.* at (d)(1).
9. Sukhatme, Liora, Note, *Deterring Fraud: Mandatory Disclosure and the FDA Drug Approval Process*, 82 N.Y.U L. Rev. 1210, 1221 (2007) (“Action letters ... only become public upon the approval of a drug. Consequently, if a drug is never approved, the letters remain confidential.”).
10. 73 Fed. Reg. at 39610.