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FDA/SEC INITIATIVE ON SECURITIES DISCLOSURE

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Highlights of the Seminar

- Summary of the initiative
- Perspectives of an FDA practitioner
- Perspectives of an SEC practitioner
- Perspectives of regulated companies
- Recommendations to consider

Summary of the Initiative

Presented by David Korn

FDA Reporting "Violations" to SEC

- Any FDA employee can now initiate a process for referring a potential violation to SEC
  - FDA unlikely to monitor corporate communications systematically
  - BUT individual reviewers and investigators may watch specific companies
  - SEC (and others) may contact FDA
- FDA's Office of the Chief Counsel will notify the Deputy Director of SEC's Division of Enforcement

Sharing of Non-Public Information

- Certain employees are given "blanket" authorization to share confidential information with SEC
  - "Trade secrets" not included (statutory bar)
  - "Trade secrets" are distinct from "confidential commercial information" and other records
- FDA can also share internal information (*i.e.*, things other than what a company submits)

Other Elements of the Initiative

- Designated liaison officers for SEC to contact in each FDA Center and Office of Regulatory Affairs
  - Facilitates SEC inquiries and coordination
- Training initiatives in both agencies
  - Sensitizes FDA employees to SEC issues
- Enhanced use of electronic communications
  - Accelerates communications

What Has Changed?

- Heightened awareness of disclosure issues
- Identified points of contact for both SEC and FDA
- Streamlined information sharing

Perspectives of an FDA Practitioner

Presented by Bill Vodra

What Information Does FDA Share with the Public?

- Nothing about products during the R&D period
- During product approval process --
  - Safety and effectiveness summaries
  - Approvability and approval status (but not rejection)
- NEVER trade secrets
- RARELY confidential commercial information
- NEVER information about ongoing investigations or pending enforcement actions

What Might FDA Share with SEC? (A) Information Submitted by a Regulated Company

- Information on product R&D
  - Target uses; status and interim results of studies
- Information on products pending approval
  - Results of studies; integrated safety summary
- Post-approval information
  - Adverse events and emerging safety issues
  - Field alerts and possible recalls
  - Advertising and promotional labeling

What Might FDA Share with SEC? (B) Information Not Necessarily Known to a Company

- Complaints submitted by third parties (consumers, competitors, plaintiffs' lawyers, media, Congress)
- Technical reviews by FDA experts
- Status of products under review
- FDA Investigations of a company
- Pending or proposed enforcement activities

Situations in Which FDA May Become More Involved

- If FDA sees statements about a product or company that are inconsistent with FDA filings
- If FDA sees statements that mischaracterize
  - Results of studies
  - Regulatory status of a product or company
  - Statements or positions of agency personnel

How Might FDA be Different?

- Will FDA employees use SEC as a tool to obtain other objectives?
- Will SEC more freely ask FDA questions about statements made in corporate filings to SEC?
- Will FDA become more wary about making informal statements to companies about status of products or compliance?

Perspectives of an SEC practitioner

Presented by Rick Baltz

Duty vs. “Desire” to Disclose

Duty to Disclose:

There is no affirmative duty to disclose material information simply because it exists . . .

Exceptions to the Rule:

- When SEC has a line item requirement, or
- When necessary to correct a prior statement that remains “alive” in market (and was inaccurate at the time it was made)

Duty to Update Prior Statements?

- Courts and law are divided as to when there is a duty to update:
  - No duty to update information that was correct at time disclosed
  - May be a duty to update such information if, by its nature, it contemplated updating
- Sarbanes-Oxley Act contemplates more “real time” disclosures

The Tough Choice

- Corporation and any insiders may not trade when material information is not disclosed
- The choice:
  - Disclose and permit the corporation and key employees to trade, or
  - Suspend trading by the corporation and key insiders until the information is made public or becomes immaterial
- Secrecy always runs risks of leaks and/or illegal insider trading

When is Information Material?

- What is “information” in context for FDA dialogue?
  - The authority of the FDA speaker
  - The formality of the FDA communication
  - The tentativeness of the FDA position
  - The potential consequences of the FDA position
  - The opportunity and ability to change FDA’s mind
- Does it alter the “total mix” of information?

Of Course

- Once a company decides to speak it has a duty to speak truthfully and not mislead
- No selective disclosure of material, non-public information

How Might SEC be Different?

- Will SEC question statements made in corporate filings regarding FDA matters and developments?
- Will SEC more frequently follow-up on other public statements made by companies in press releases and other public events?
- Will SEC "supplement" its review capabilities with FDA staff?

Perspectives of Regulated Companies

Presented by Steve Parker

How Does This Affect Day-to-Day Life? Types of Disclosures:

- Approval/non-approval (the way most people think about the initiative)
- There are others:
  - Recalls and other market situations
  - Filing/withdrawal
  - Developments in the clinic or factory
  - Investigations (initiation, development, leaks)
  - Litigation

How About When Companies WANT to Disclose?

- Even when no legal duty to disclose, corporations will want to issue statements to
  - Further business objectives
  - Promote products and services
  - Facilitate information flow
  - Keep markets and investors informed

What Can/Should a Company Say?

- How much detail?
  - Satisfying SEC vs. providing greater transparency
  - Greater detail heightens duty to update
  - More detail invites FDA criticism/reaction
    - Promote products
    - Dilutes negative news
    - Predict favorable FDA action

Recommendations To Consider

1. Reassess Your Disclosure Controls and Procedures

- CEO and CFO Certifications
- Disclosure/Regulation FD Policies:
  - Disclosure Committee
  - Monitor information in market

2. Involve Legal and Regulatory Personnel

- Review of proposed public statements (press releases, SEC filings)
- Support investor relations personnel with SEC and FDA experts

3. Don't Blindside the FDA

- Consider informing FDA about press releases before/when issued
- If you are worried about FDA's reaction, think about that reaction when FDA gets a call from SEC
- Should a company try to pre-clear a public statement?

4. Clarify Communications with FDA

- Regulatory liaison should understand the risks of ambiguity and know when to press for clarity
- Disclosure issues should be raised with FDA officials only after decision made to disclose

5. Assure Public Statements Are Not Misleading

- Regulatory liaison should be unambiguous within company
- Corporate spokespersons should be trained to talk precisely about FDA process

Open For Questions

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