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Part III

Securities and Exchange Commission

**17 CFR Parts 231, 241, and 271
Commission Guidance Regarding
Accounting for Sales of Vaccines and
Bioterror Countermeasures to the Federal
Government for Placement Into the
Pediatric Vaccine Stockpile or the
Strategic National Stockpile; Final Rule**

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 231, 241, and 271

[Release Nos. 33-8642; 34-52885; IC-27178]

Commission Guidance Regarding Accounting for Sales of Vaccines and Bioterror Countermeasures to the Federal Government for Placement Into the Pediatric Vaccine Stockpile or the Strategic National Stockpile

AGENCY: Securities and Exchange Commission.

ACTION: Interpretation.

SUMMARY: The Securities and Exchange Commission (Commission) is publishing this interpretive release with respect to accounting for sales of vaccines and bioterror countermeasures to the Federal government for placement into stockpiles related to the Vaccines for Children Program or the Strategic National Stockpile.

DATES: *Effective:* December 5, 2005.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Introduction

The Commission is committed to addressing any unintended consequences of accounting requirements that could impair the nation's ability to create and maintain sufficient supplies of various vaccines and bioterror countermeasures (vaccines). The Commission is aware that questions have been raised about the timing of the vaccine manufacturers' revenue recognition for vaccines placed into stockpiles related to the Vaccines for Children Program and the Strategic National Stockpile. Additionally, concerns have been expressed that Commission guidance, which may require revenue recognition to be delayed beyond the period in which the vaccine is placed in the stockpile in some circumstances, may have the unintended consequence of causing some vaccine manufacturers to decline to participate in these critical stockpile programs. Although the Commission is not aware of any instance to date of a vaccine manufacturer declining to participate in these programs based on the resulting accounting, the

Commission is publishing this guidance to remove the accounting questions from the debate.

Government vaccine stockpile programs are unique in many respects. For example, the primary objective of purchasing the vaccines is not to take delivery but rather to be able to require delivery on a moment's notice. The hope of both parties to these contracts is that the vaccines will never be needed and thus never delivered. Another unique characteristic of vaccine stockpile programs is the critical public policy objective of safeguarding the public health in the event of potentially catastrophic disease outbreaks. An additional unusual characteristic of vaccine stockpiles is the need for rotation of the stockpile due to limited shelf life. For these and other reasons, the Commission limits this guidance to the vaccines enumerated below (enumerated vaccines).

II. The Application of Generally Accepted Accounting Principles for Revenue Recognition to Vaccine Stockpiles

The Commission historically has recognized pronouncements of the Financial Accounting Standards Board (FASB) as authoritative in the absence of any contrary determination by the Commission.¹ More recently, in Financial Reporting Release No. 70,² the Commission announced its determination that the FASB and its parent organization, the Financial Accounting Foundation, satisfied the criteria in section 108 of the Sarbanes-Oxley Act of 2002³ and section 19(b) of the Securities Act of 1933⁴ and, accordingly, FASB's financial accounting and reporting standards are recognized as "generally accepted" for purposes of the Federal securities laws. As a result, registrants are required to comply with those standards in preparing financial statements filed with the Commission, unless the Commission provides otherwise.⁵

Although no specific guidance has been published by the FASB related to revenue recognition for vaccine stockpiles, general criteria for revenue recognition are discussed in the FASB's Concepts Statements. Statement of

¹ Rule 4-01(a)(1) of Regulation S-X, 17 CFR 210.4-01(a)(1). See Accounting Series Release ("ASR") No. 150 (December 20, 1973) and ASR No. 4 (April 25, 1938).

² Release Nos. 33-8221; 34-47743; IC-26028; FR-70 (April 25, 2003) ("FR-70"); 68 FR 23333 (May 1, 2003).

³ 15 U.S.C. 7218.

⁴ 15 U.S.C. 77s(b).

⁵ See FR-70; Rule 4-01(a)(1) of Regulation S-X, 17 CFR 210.4-01(a)(1).

Financial Accounting Concepts No. 5, *Recognition and Measurement in Financial Statements of Business Enterprises* (Concepts Statement 5) identifies two criteria necessary for revenue recognition: the revenue must be realized or realizable and earned.⁶ Concepts Statement 5 goes on to explain that "revenues are considered to have been earned when the entity has substantially accomplished what it must do to be entitled to the benefits represented by the revenues"⁷ and that the two conditions for revenue recognition are "usually met by the time product or merchandise is delivered."⁸

In 1986, in Securities Exchange Act Release No. 23507 and Accounting and Auditing Enforcement Release No. 108, *In the Matter of Stewart Parness* (AAER 108), the Commission set forth criteria to be met in order to recognize revenue when delivery has not occurred.⁹ Of the seven criteria AAER 108 set forth as necessary for revenue recognition in the absence of delivery (commonly referred to as "bill and hold"), transfers of vaccines to government stockpiles sometimes do not satisfy the following two:

- There must be a fixed schedule for delivery of the goods; and
- The ordered goods must have been segregated from the seller's inventory and not be subject to being used to fill other orders.¹⁰

III. Current Commission Guidance

Notwithstanding the Commission's previous guidance discussed above, the Commission will not object if vaccine manufacturers recognize revenue from the sale of enumerated vaccines related to Federal governmental stockpile programs if the arrangements meet the applicable revenue recognition criteria specified under generally accepted accounting principles and Commission rules and regulations, other than for the requirements associated with product delivery and inventory segregation noted above, so long as disclosures are provided that allow for a clear understanding by investors of the subject transactions, the related accounting, and the effect of this alternative accounting method in the financial statements.

The following vaccines are subject to this Release when sold to the Federal

⁶ See Concepts Statement 5, ¶ 83 (a) and (b).

⁷ Concepts Statement 5, ¶ 83(b).

⁸ Concepts Statement 5, ¶ 84(a).

⁹ See *In the Matter of Stewart Parness*, AAER 108 (August 5, 1986). The Commission staff reiterated this guidance in Staff Accounting Bulletin (SAB) Topic 13 in 1999 through the issuance of SAB 101.

¹⁰ See SAB Topic 13. A. 3 and AAER 108.

government for purposes of placing the vaccines into a Federal governmental vaccine stockpile (enumerated vaccines):

- Childhood disease vaccines;
- Influenza vaccines; and
- Other vaccines and

countermeasures sold to the Federal government for placement in the Strategic National Stockpile.

The Commission would not object if a registrant that sells enumerated vaccines elects this alternative accounting method beginning in the first fiscal quarter of the registrant's next fiscal year. If elected, the change in accounting represents a change in accounting principle under FASB Statement No. 154, *Accounting Changes and Error Corrections*. No preferability letter would be required if an accounting change is made solely in response to the adoption of the alternative method described above.

Any financial statements filed with the Commission before adoption of the provisions of this announcement would be subject to the disclosure provisions of SAB Topic 11-M, *Disclosure of the Impact That Recently Issued Accounting Standards Will Have on the Financial Statements of a Registrant When Adopted in a Future Period*.

Due to the uniqueness of the vaccine stockpile programs as discussed above, the alternative method is available only to the sales of enumerated vaccines by vaccine manufacturers and may not be extended by analogy to other circumstances.

IV. Financial Statement and Other Disclosures

If the alternative accounting method is elected, the Commission believes that sufficient disclosures should be provided to allow for a clear understanding by investors of the

subject transactions, related accounting, and the effect of the alternative accounting method in the financial statements. The following disclosures should be considered:

A. Material terms and conditions of contracts for which the alternative accounting method was selected, including all fees received and a description of each enumerated vaccine product that the vaccine manufacturer sells to vaccine stockpiles. The vaccine manufacturer should also describe the nature of its continuing involvement with the stockpiles for enumerated vaccine products for which revenue has been recognized, such as stock rotation. Additionally, the election of this alternative form of revenue recognition would generally be a significant accounting policy under APB Opinion No. 22, *Disclosure of Accounting Policies*. Vaccine manufacturers should clearly disclose that this alternative policy applies only to enumerated vaccine product sales.

B. Disclosures quantifying the effects of using the alternative policy on relevant balance sheet and income statement captions, including revenue, cost of sales, inventory and deferred revenue.

C. Supplemental disclosure of the market value of inventory available to be rotated out of vaccine stockpiles and of sales to third parties that were filled from vaccine stockpiles.

D. Supplemental disclosure of enumerated vaccine product quantities and related product sales revenue for enumerated vaccines actually delivered from stockpiles to the CDC or other party for use during the period (*i.e.*, delivered out of stockpiles).

List of Subjects in 17 CFR Parts 231, 241, and 271

Securities.

Amendments to the Code of Federal Regulations

■ For the reasons set out in the preamble, the Commission is amending Title 17, chapter II of the Code of Federal Regulations as set forth below:

PART 231—INTERPRETATIVE RELEASES RELATING TO THE SECURITIES ACT OF 1933 AND GENERAL RULES AND REGULATIONS THEREUNDER

■ Part 231 is amended by adding Release No. 33-8642 and the release date of December 5, 2005 to the list of interpretive releases.

PART 241—INTERPRETATIVE RELEASES RELATING TO THE SECURITIES EXCHANGE ACT OF 1934 AND GENERAL RULES AND REGULATIONS THEREUNDER

■ Part 241 is amended by adding Release No. 34-52885 and the release date of December 5, 2005 to the list of interpretive releases.

PART 271—INTERPRETATIVE RELEASES RELATING TO THE INVESTMENT COMPANY ACT OF 1940 AND GENERAL RULES AND REGULATIONS THEREUNDER

■ Part 271 is amended by adding Release No. IC-27178 and the release date of December 5, 2005 to the list of interpretive releases.

By the Commission.

Dated: December 5, 2005.

Jonathan G. Katz,

Secretary.

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