

(B) The market's prices are routinely disseminated in a widely distributed industry publication and are routinely consulted by industry participants in pricing cash market transactions.

(ii) *Notification.* An electronic trading facility operating in reliance on section 2(h)(3) of the Act shall notify the Commission when it has reason to believe that:

(A) Cash market bids, offers or transactions are directly based on, or quoted at a differential to, the prices generated on the market on a more than occasional basis;

(B) The market's prices are routinely disseminated in a widely distributed industry publication and are routinely consulted by industry participants in pricing cash market transactions; or

(C) The market holds itself out to the public as performing a price discovery function for the cash market for the commodity.

(iii) *Price discovery determination.* Following receipt of a notice under paragraph (c)(2)(ii) of this section, or on its own initiative, the Commission may notify an electronic trading facility operating in reliance on section 2(h)(3) of the Act that the trading facility appears to meet the criteria for performing a significant price discovery function under paragraph (c)(2)(i)(A) or (B) of this section. Before making a final price discovery determination under this paragraph, the Commission shall provide the electronic trading facility with an opportunity for a hearing through the submission of written data, views and arguments. Any such written data, views and arguments shall be filed with the Secretary of the Commission in the form and manner and within the time specified by the Commission. After consideration of all relevant matters, the Commission shall issue an order containing its determination whether the electronic trading facility performs a significant price discovery function under the criteria of paragraph (c)(2)(i)(A) or (B) of this section.

(iv) *Price dissemination.* (A) An electronic trading facility that the Commission has determined performs a significant price discovery function under paragraph (c)(2)(iii) of this section shall disseminate publicly and on a daily basis all of the following information with respect to transactions executed in reliance on the exemption:

(1) Contract terms and conditions, or a product description, and trading conventions, mechanisms and practices;

(2) Trading volume by commodity and, if available, open interest; and

(3) The opening and closing prices or price ranges, the daily high and low prices, a volume-weighted average price

that is representative of trading on the trading facility, or such other daily price information as proposed by the facility and approved by the Commission.

(B) The trading facility shall make such information readily available to the news media and the general public without charge no later than the business day following the day to which the information pertains.

(v) *Modification of price discovery determination.* A trading facility that the Commission has determined performs a significant price discovery function under paragraph (c)(2)(iii) of this section may petition the Commission at any time to modify or vacate that determination. The petition shall contain an appropriate justification for the request. The Commission, after notice and opportunity for a hearing through the submission of written data, views and arguments, shall by order grant, grant subject to conditions, or deny such request.

(3) *Required representation.* * * *

Issued in Washington, DC, on July 13, 2004, by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 04-16319 Filed 7-19-04; 8:45 am]

BILLING CODE 6351-01-P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 230

[Release No. 33-8442; File No. S7-17-04]

RIN 3235-AJ03

Covered Securities Pursuant to Section 18 of the Securities Act of 1933

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Securities and Exchange Commission ("Commission") is adopting an amendment to a rule under section 18 of the Securities Act of 1933 ("Securities Act"). The purpose of the amendment is to designate options listed on the International Securities Exchange, Inc. ("ISE") as covered securities. Covered securities under section 18 of the Securities Act are exempt from State law registration requirements.

DATES: *Effective Date:* August 19, 2004.

FOR FURTHER INFORMATION CONTACT: Kelly Riley, Assistant Director, (202) 942-0752, Gordon Fuller, Counsel to the Assistant Director, (202) 942-0792 or Brian Trackman, Attorney, (202) 942-7951, Division of Market Regulation,

Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549-1001.

SUPPLEMENTARY INFORMATION:

I. Introduction

In 1996, Congress amended section 18 of the Securities Act to exempt from State registration requirements securities listed, or authorized for listing, on the New York Stock Exchange ("NYSE"), the American Stock Exchange ("Amex"), or the National Market System of the Nasdaq Stock Market ("Nasdaq/NMS") (collectively, the "Named Markets"), or any national securities exchange determined by the Commission to have substantially similar listing standards to those markets.¹ More specifically, section 18(a) of the Securities Act provides that "no law, rule, regulation, or order, or other administrative action of any State * * * requiring, or with respect to, registration or qualification of securities * * * shall directly or indirectly apply to a security that—(A) is a covered security."² Covered securities are defined in section 18(b)(1) of the Securities Act to include those securities listed, or authorized for listing, on the Named Markets, or securities listed, or authorized for listing on a national securities exchange (or tier or segment thereof) that has listing standards that the Commission determines by rule are "substantially similar" to the Named Markets.³

The Commission adopted Rule 146 pursuant to section 18(b)(1)(B) of the Securities Act.⁴ Rule 146(b) lists those national securities exchanges, or segments or tiers thereof that the Commission has determined to have listing standards substantially similar to those of the Named Markets, and thus securities listed on such exchanges are covered securities.⁵ The ISE has petitioned the Commission to amend Rule 146(b) to determine that its listing standards for securities listed on the ISE are substantially similar to those of the Named Markets and, accordingly, that securities listed pursuant to such listing

¹ See National Securities Markets Improvement Act of 1996, Public Law No. 104-290, 110 Stat. 3416 (October 11, 1996).

² 15 U.S.C. 77r(a).

³ 15 U.S.C. 77r(b)(1). In addition, securities of the same issuer that are equal in seniority or senior to a security listed on a Named Market or national securities exchange designated by the Commission as having substantially similar listing standards to a Named Market are covered securities for purposes of section 18 of the Securities Act. 15 U.S.C. 77r(b)(1)(C).

⁴ Securities Act Release No. 7494, Securities Exchange Act Release No. 39542 (January 13, 1998), 63 FR 3032 (January 21, 1998).

⁵ 17 CFR 230.146(b).

standards are covered securities for purposes of section 18(b) of the Securities Act.⁶

On March 22, 2004, the Commission issued a release proposing to amend Rule 146(b) to designate options listed on the ISE as covered securities for purposes of section 18(a) of the Securities Act.⁷ The Commission solicited comment on the proposal, and received one comment letter in response to the proposal.⁸

After careful comparison, the Commission concludes that the current listing standards of the ISE are substantially similar to the listing standards of the Amex. Accordingly, the Commission today is amending Rule 146(b) to designate options listed on the ISE as covered securities under section 18(b)(1) of the Securities Act. Amending Rule 146(b) to include options listed on ISE as covered securities will exempt those securities from State registration requirements as set forth under section 18(a) of the Securities Act.

II. Background

In 1998, the Chicago Board Options Exchange, Inc. ("CBOE"), Pacific Exchange, Inc. ("PCX"), the Philadelphia Stock Exchange, Inc. ("Phlx"), and the Chicago Stock Exchange ("CHX") petitioned the Commission to adopt a rule determining that specified portions of the exchanges' listing standards were substantially similar to the listing standards of the Named Markets.⁹ In response to the petitions, and after extensive review of the petitioners' listing standards, the Commission adopted Rule 146(b), determining that the listing standards of the CBOE, Tier 1 of the PCX, and Tier 1 of the Phlx were substantially similar to those of the Named Markets and that securities listed pursuant to those standards would be deemed covered

securities for purposes of section 18 of the Securities Act.¹⁰

In its petition, ISE has asked the Commission to amend Rule 146(b) based on a determination that its listing standards are substantially similar to those of the Named Markets so that securities listed on ISE will be "covered securities" under section 18(b) of the Securities Act.¹¹ The ISE currently lists only standardized options issued and guaranteed by the Options Clearing Corporation ("OCC") that are already listed on at least one of the other options exchanges named in section 18(b)(1)(A) of the Securities Act or Rule 146—*i.e.*, Amex, CBOE, PCX and Phlx. These options are by definition "covered securities" for purposes of section 18 of the Securities Act. ISE, however, stated that it may in the future list standardized options issued and guaranteed by OCC that are not listed on one of the other options exchanges specified in section 18(b)(1)(A) of the Securities Act or Rule 146. Accordingly, the ISE requested that the Commission amend Rule 146(b) to designate securities listed on ISE as covered securities for purposes of section 18 of the Securities Act.

III. Comment Letters

As noted above, the Commission received one comment letter in response to the proposed rule amendment, which supported ISE's petition to amend Rule 146(b).¹² The OCC Letter noted that designating options listed on the ISE as "covered securities" would place the ISE on an equal competitive footing with other options exchanges whose listed securities are presently exempt from State blue sky laws. The OCC agreed with the Commission's preliminary view that ISE's selection and maintenance requirements for underlying securities are substantially similar to those of Amex. Finally, in response to the Commission's request for comment on whether the absence of an express provision in ISE's rules that it will monitor news sources for information indicating that an underlying security no longer meets the

requirements for continued approval should impact the Commission's determination of whether ISE's rules are "substantially similar" to Amex's rules, the OCC Letter explained that the absence of such a provision in the ISE maintenance requirements is a difference without substance. The OCC expressed its view that, because the ISE is obligated under sections 6 and 19(g) of the Securities Exchange Act of 1934 ("Exchange Act") to enforce its rules, including its maintenance requirements, the ISE is required to monitor for corporate events that render a security ineligible to underlie ISE listed options.

IV. Discussion

The Commission has reviewed the ISE listing standards for options traded on the ISE and determines that they are substantially similar to those of Amex. The Commission notes that, under section 18(b)(1)(A) of the Securities Act, the Commission has the authority to compare the listing standards of a petitioner with those of either the NYSE, Amex, or Nasdaq/NMS. Because Amex is the only Named Market that lists standardized options, the Commission compared ISE's listing standards to the listing standards applicable to options traded on the Amex.

In addition, the Commission has interpreted the "substantially similar" standard to require listing standards at least as comprehensive as those of the Named Markets.¹³ To the extent that the ISE's listing standards are stricter than those of Amex, the Commission may determine that they meet the substantially similar standard. Finally, the Commission notes that differences in language or approach do not necessarily lead to a determination that the listing standards of the petitioner are not substantially similar to those of a Named Market.

The Commission reviewed ISE's listing standards for each class of security it trades, specifically equity options and index options. Using the approach outlined above, the Commission concludes that currently the listing standards of the ISE are substantially similar to the listing standards of the Amex.

With respect to equity options, the ISE listing and maintenance requirements closely track the corresponding Amex provisions.¹⁴ Specifically, the ISE's original listing requirements pertaining to the public

⁶ See letter from Michael Simon, Senior Vice President and General Counsel, ISE, to Jonathan G. Katz, Secretary, Commission, dated October 9, 2003.

⁷ Securities Act Release No. 8404, 69 FR 16154 (March 26, 2004) ("Proposing Release").

⁸ See letter from William H. Navin, Executive Vice President and General Counsel, Options Clearing Corporation, to Jonathan G. Katz, Secretary, Commission, dated April 23, 2004 ("OCC Letter").

⁹ See letter from David P. Semak, Vice President, Regulation, PCX, to Arthur Levitt, Jr., Chairman, Commission, dated November 15, 1996; letter from Alger B. Chapman, Chairman, CBOE, to Jonathan G. Katz, Secretary, Commission, dated November 18, 1996; letter from J. Craig Long, Esq., Foley & Lardner, Counsel to CHX, to Jonathan G. Katz, Secretary, Commission, dated February 4, 1997; and letter from Michele R. Weisbaum, Vice President and Associate General Counsel, Phlx, to Jonathan G. Katz, Secretary, Commission, dated March 31, 1997.

¹⁰ Securities Act Release No. 7494, Securities Exchange Act Release No. 39542 (January 13, 1998), 63 FR 3032 (January 21, 1998). Review of CHX's listing program, including its listing standards and operations, is ongoing. CHX has petitioned the Commission to amend Rule 146(b) to include Tier 1 of CHX's listing standards. See letter from Paul B. O'Kelly, Executive Vice President, Market Regulation and Legal, CHX, to Jonathan G. Katz, Secretary, Commission, dated May 17, 2000.

¹¹ The Commission notes that, currently, the ISE lists only standardized options and, accordingly, only has listing standards for equity and index options.

¹² See *supra* note 8.

¹³ Securities Act Release No. 7422, Securities Exchange Act Release No. 38728 (June 9, 1997), 62 FR 32705 (June 17, 1997).

¹⁴ Compare ISE Rules 502 and 503 with Amex Rules 915 and 916.

float, distribution of shares and trading volume of the underlying security are identical to those of the Amex.¹⁵ The ISE and Amex also impose the same initial listing and maintenance requirements for options on American Depositary Receipts (“ADRs”), International Funds, Restructured Companies, Exchange-Traded Fund shares (“ETFs”),¹⁶ and Trust Issued Receipts.¹⁷ The only difference, identified in the Proposing Release, between the ISE and Amex original listing standards was a provision in the Amex rules that permits Amex members to propose the listing of an option that otherwise meets established listing requirements. ISE rules do not contain a similar provision. The Commission has determined that because this difference does not impact the quality of ISE’s listing standards, it does not render ISE’s listing standards less comprehensive than Amex’s listing standards.¹⁸ Further, as noted above, differences in language or approach of listing standards are not dispositive.

With regard to the maintenance standards for equity options, the ISE’s maintenance requirements for its equity options substantively track those of the Amex.¹⁹ With respect to the underlying security of an equity option, the ISE and Amex have identical maintenance requirements regarding the number of publicly traded shares, their distribution, trade volumes and market price. Failure to meet any one of these criteria may result in delisting the option.²⁰

¹⁵ See *id.* The Commission notes that no exchange has standards establishing qualifications for issuers of exchange-traded options because all options are issued by the OCC. All options issued by the OCC have the equal protection of OCC’s backup system of clearing members’ obligations, margin deposits and clearing funds.

¹⁶ ETFs are defined under Amex Rule 915 to include “shares or other securities that are principally traded on a national securities exchange or through the facilities of a national securities association and reported as a national market security, and that represent an interest in a registered investment company organized as an open-end management investment company, a unit investment trust or a similar entity which holds securities constituting or otherwise based on or representing an investment in an index or portfolio of securities. * * *” See Amex Rule 915 Commentary .06. These securities are referred to as “Fund Shares” in the ISE rules. See ISE Rule 502(h).

¹⁷ Compare subsections (c), (f)–(h), and (j) of ISE Rule 502 with Subsections .03–.07 of Amex Rule 915, and Subsections (g)–(j) of ISE Rule 503 with Subsections .06–.09 of Amex Rule 916.

¹⁸ The Proposing Release contains a more detailed description of the Commission’s analysis comparing ISE’s listing and maintenance standards for equity options to those of Amex. See Securities Act Release No. 8404 (March 22, 2004), 69 FR 16154 (March 26, 2004).

¹⁹ Compare ISE Rule 503 with Amex Rule 916.

²⁰ See ISE Rule 503.

Both Amex and ISE may withdraw approval for options trading if the issuer of an underlying security that is principally traded on a national securities exchange is delisted from trading on that exchange and neither meets National Market System (“NMS”) criteria nor is traded through the facilities of a national securities association. Amex and ISE may also withdraw approval for options trading on a security that is principally traded through facilities of a national securities association, if such security is no longer designated as an NMS security.²¹ Likewise, the ISE and Amex impose the same maintenance requirements for continued listing of options on ADRs, ETFs, Trust Issued Receipts, and Holding Company Depositary Receipts.²²

The Commission noted in the Proposing Release that ISE did not have an express provision requiring the ISE to monitor on a daily basis news sources for information of corporate actions, which may indicate that an underlying security no longer meets requirements for continued approval, while Amex rules did have this express provision. Because ISE is obligated under sections 6 and 19(g) of the Exchange Act to comply with its own rules, which necessitates ISE monitoring corporate events that have a bearing on whether an underlying security satisfies ISE’s listing standards, the Commission finds that the absence of such express provision does not represent a significant enough difference between the ISE and the Amex to change our conclusion that their listing standards are substantially similar. The Commission notes that the OCC supported this conclusion by stating that “[t]he fact that ISE’s rules do not describe specifically how ISE will conduct such monitoring does not mean that ISE’s maintenance standards are less comprehensive.”²³

With respect to index options, the Commission finds that the ISE and the Amex have substantially similar requirements for stock indices that may underlie index options. With regard to broad-based index options, both the ISE and the Amex require that the listing of a class of options on a new underlying index must be filed with the Commission as a proposed rule change under section 19(b) of the Exchange Act.²⁴ Furthermore, the Commission

²¹ See ISE Rule 503(b)(6); Amex Rule 916 Commentary .01(6).

²² Compare subsections (g)–(j) of ISE Rule 503 with subsections .06–.09 of Amex Rule 916.

²³ See *supra* note 8.

²⁴ See ISE Rule 2002(a), Amex Rule 901C.01.

finds that the exchanges have substantially similar provisions for the designation of narrow-based indices as eligible to underlie index options, including rules that allow certain options to be traded on certain narrow-based indices using an expedited procedure, which involves submitting to the Commission a Form 19b–4(e) under Rule 19b–4(e) of the Exchange Act.²⁵ The listing and maintenance requirements for component securities comprising narrow-based index options listed on the ISE appear in all material respects to be substantially similar to those of the Amex.²⁶ Specifically, the ISE and the Amex appear to have substantially similar criteria for index components relating to market value, trading volume, calculation of the index, and inclusion of non-U.S. component securities or ADRs.²⁷ In addition, the Commission believes that ISE and Amex requirements for the index regarding weighting, index components, rebalancing, information barriers maintained by broker-dealers, and the dissemination of index values are substantially similar.²⁸ Likewise, the ISE rules setting forth position and exercise limits, margin requirements, and settlement terms applicable to index options are substantially similar to those of the Amex.²⁹ Accordingly, the Commission has determined that the listing standards of the ISE and the Amex for index options are substantially similar.

Therefore, the Commission has determined that the ISE’s listing standards are substantially similar to a Named Market and is amending Rule 146(b) to reflect this determination, designating options listed on the ISE as “covered securities” for purposes of section 18 of the Securities Act.

The Commission notes that designating ISE options as covered securities under Rule 146(b)(1) subjects ISE’s listing standards to Rule 146(b)(2). Rule 146(b)(2) under the Securities Act conditions the designation of securities as “covered securities” under Rule 146(b)(1) on the identified exchange’s listing standards continuing to be substantially similar to those of the

²⁵ Compare ISE Rule 2002(b) with Amex Rule 901C.02.

²⁶ Compare ISE Rules 502, 2002(c) with Amex Rules 915, 901C.02(d).

²⁷ Compare ISE Rule 2002(b) with Amex Rule 901C.02.

²⁸ Compare ISE Rules 2002 and 2003 with Amex Rule 901C.

²⁹ Compare ISE Rules 413, 417, 418, 709, 1102, 2004–2010, 2012 with Amex Rules 462, 903C, 904C, 905C, 909C, 916C, 918C, 951C, and 980C. The ISE and Amex’s disclaimer provisions relating to index options are also substantially similar. Compare ISE Rule 2011 with Amex Rule 902C.

Named Markets. In essence, Congress intended for the Commission to monitor the listing and maintenance requirements of the exchanges, consistent with our supervisory responsibility under the Exchange Act, to evaluate the continued integrity of these markets and the protection of investors. Thus, under Rule 146(b)(2), the designation of its securities as covered securities is conditioned on the ISE maintaining listing standards that are substantially similar to those of the Named Markets.

V. Consideration of Promotion of Efficiency, Competition and Capital Formation

As required under the Securities Act,³⁰ the Commission has considered the proposed rule's impact on efficiency, competition and capital formation. Options exchanges are prohibited by Commission rule from prohibiting, conditioning or limiting the listing of any stock options class first listed on another options exchange.³¹ Nevertheless, options exchanges do compete for listings of non-equity options such as index options. The Commission believes that designating ISE-listed options as "covered securities" by amending Rule 146(b) will permit ISE to better compete for new options and listings, which will increase competition and, potentially, the overall liquidity of the U.S. securities markets. The Commission does not, however, believe that the amendment to Rule 146(b) will have any impact—positive or negative—on capital formation because options are not used by issuers to raise money. The Commission solicited comment on the proposed amendment's effect on competition, efficiency and capital formation. No comments were received. Thus, the Commission concludes that the proposed amendment to Rule 146(b) would promote efficiency and competition.

VI. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 does not apply because the proposed amendment to Rule 146(b) does not impose recordkeeping or information collection requirements or other collection of information, which require the approval of the Office of Management and Budget under 44 U.S.C. 3501 *et seq.*

VII. Cost and Benefits of Proposed Rulemaking

Congress amended section 18 of the Securities Act to exempt covered securities from State registration requirements. Covered securities are those listed on the Named Markets or any other national securities exchange determined by the Commission to have substantially similar listing standards to the Named Markets.³² Consistent with statutory authority, the Commission has determined that the listing standards of the ISE are substantially similar to those of the Amex, the only Named Market that lists standardized options. Options listed on the ISE are therefore covered securities subject only to Federal regulation.

By exempting options listed on ISE from State law registration requirements, the Commission expects that the listing process will become easier by avoiding duplicative regulation. Moreover, we also expect adoption of the rule to minimize the administrative burden ISE and the OCC face inasmuch as compliance with State registration requirements is preempted.

The Commission also believes that the amendment to Rule 146(b) will permit ISE to compete with other markets whose options are exempt from State registration requirements for new options products and listings. This result has the potential to enhance competition and liquidity, thus benefiting market participants and the public.

The Commission does not believe that there are any significant costs to investors associated with the preemption of State registration requirements for options listed with the ISE. The Commission notes that there may be some cost to investors through the loss of the benefits of State registration and oversight, although the cost is difficult to quantify and, in any event, is unlikely to be significant. Furthermore, we believe that Congress contemplated this potential cost in relation to the economic benefits of exempting covered securities from State regulation. The Commission solicited comment as to the costs and benefits associated with the proposed amendment. No comments were received.

VIII. Regulatory Flexibility Act Certification

In the Proposing Release,³³ the Commission certified, pursuant to section 605(b) of the Regulatory

Flexibility Act,³⁴ that amending Rule 146(b) would not have a significant economic impact on a substantial number of small entities. The Commission solicited comment as to the nature of any impact on small entities, including empirical data to support the extent of such impact costs and benefits associated with the proposed amendment. No comments were received.

IX. Statutory Authority

The Commission is amending Rule 146(b) pursuant to the Securities Act of 1933 (15 U.S.C. 77a *et seq.*), particularly sections 18(b)(1)(B) and 19(a) (15 U.S.C. 77r(b)(1)(B) and 77s(a)).

List of Subjects in 17 CFR Part 230

Securities.

Text of the Rule

■ For the reasons set forth in the preamble, title 17, chapter II of the Code of Federal Regulations is amended as follows:

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

■ 1. The authority citation for part 230 continues to read, in part, as follows:

Authority: 15 U.S.C. 77b, 77c, 77d, 77f, 77g, 77h, 77j, 77r, 77s, 77z-3, 77sss, 78c, 78d, 78j, 78l, 78m, 78n, 78o, 78t, 78w, 78ll(d), 78mm, 79t, 80a-8, 80a-24, 80a-28, 80a-29, 80a-30, and 80a-37, unless otherwise noted.
* * * * *

■ 2. Section 230.146 is amended by revising paragraphs (b)(1)(ii), (b)(1)(iii), and (b)(2) and by adding paragraph (b)(1)(iv) as follows:

§ 230.146 Rules under section 18 of the Act.

* * * * *
(b) * * *
(1) * * *
(i) * * *
(ii) Tier I of the Philadelphia Stock Exchange, Incorporated;
(iii) The Chicago Board Options Exchange, Incorporated; and
(iv) Options listed on the International Securities Exchange, Incorporated.

(2) The designation of securities in paragraphs (b)(1)(i) through (iv) of this section as covered securities is conditioned on such exchanges' listing standards (or segments or tiers thereof) continuing to be substantially similar to those of the NYSE, Amex, or Nasdaq/NMS.

Dated: July 14, 2004.

³⁴ 5 U.S.C. 605(b).

³⁰ 15 U.S.C. 77b(b).

³¹ See 17 CFR 240.19c-5.

³² 15 U.S.C. 77r(b)(1)(B).

³³ See *supra* note 7.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 04-16441 Filed 7-19-04; 8:45 am]

BILLING CODE 8010-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 17

[Docket No. 2003N-0308]

Civil Money Penalties Hearings; Maximum Penalty Amounts and Compliance With the Federal Civil Penalties Inflation Adjustment Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a new regulation to adjust for inflation the maximum civil money penalty amounts for the various civil money penalty authorities within our jurisdiction. We are taking this action to comply with the Federal Civil Penalties Inflation Adjustment Act of 1990 (FCPIAA), as amended.

DATES: This rule is effective on September 20, 2004.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy and Planning (HF-23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0587.

SUPPLEMENTARY INFORMATION:

I. Why Are We Revising Our Civil Money Penalty Rules?

In general, the FCPIAA (28 U.S.C. 2461, as amended by the Debt Collection Improvement Act of 1996) requires Federal agencies to issue regulations to adjust for inflation each civil monetary penalty provided by law within their jurisdiction. The FCPIAA directs agencies to adjust the civil monetary penalties by October 23, 1996, and to make additional adjustments at least once every 4 years thereafter. The adjustments are based on changes in the cost of living, and the FCPIAA defines the cost of living adjustment as:

* * * the percentage (if any) for each civil monetary penalty by which—

(1) the Consumer Price Index for the month of June of the calendar year preceding the adjustment, exceeds

(2) the Consumer Price Index for the month of June of the calendar year in which the amount of such civil monetary penalty was last set or adjusted pursuant to law. * * *

The FCPIAA also prescribes a rounding method based on the amount of the calculated increases, but states that the initial adjustment of a civil monetary penalty may not exceed 10 percent of the penalty.

The FCPIAA defines a civil monetary penalty as:

* * * any penalty, fine, or other sanction that—

(A)(i) is for a specific monetary amount as provided by Federal law; or

(ii) is a maximum amount provided for by Federal law; and

(B) is assessed or enforced by an agency pursuant to Federal law; and

(C) is assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal Courts * * *.

Congress enacted the FCPIAA, in part, because it found that the impact of civil monetary penalties had been reduced by inflation and that reducing the impact of civil monetary penalties had weakened their deterrent effect.

In the **Federal Register** of December 1, 2003 (68 FR 67094), we published a proposed rule that identified 14 civil monetary penalties that fall within our jurisdiction and are subject to adjustments under the FCPIAA. The proposal amended our civil money penalties hearing regulations at part 17 (21 CFR part 17) to establish a new § 17.2, entitled “Maximum penalty amounts” to show the current maximum civil monetary penalty amounts that were adjusted under the FCPIAA.

The proposal also revised § 17.1 which lists statutory provisions authorizing civil money penalties that were governed by the civil money penalty regulations as of August 28, 1995. The proposed revision simply updated the statutory citations.

II. What Comments Did We Receive on the Proposal?

We received two comments on the proposed rule. A description of those comments and our responses follow. To make it easier to identify comments and our responses, the word “Comment,” in parentheses, will appear before the comment’s description, and the word “Response,” in parentheses, will appear before our response. We have also numbered each comment to help distinguish between different comments. The number assigned to each comment is purely for organizational purposes and does not signify the

comment’s value or importance or the order in which it was received.

(Comment 1) One comment stated that the adjusted penalties were not severe enough to “keep crooked manufacturers from stopping their criminal acts which injure the American people.” The comment said that the penalties should be increased by another 25 percent, and claimed that some drugs have caused more harm than benefits to individuals.

The comment also made remarks concerning compensation afforded to pharmaceutical executives and the drug approval process.

(Response) As we previously stated and in the preamble to the proposed rule, the FCPIAA prescribes a formula for calculating the increase for a civil monetary penalty and states that the initial adjustment of a civil monetary penalty may not exceed 10 percent of the penalty. (See 68 FR at 67094.) Thus, while higher civil monetary penalties might be a better deterrent, the FCPIAA does not authorize increases in penalties greater than 10 percent. Instead, the FCPIAA creates a framework for calculating and limiting the increases to a civil monetary penalty, and so the comment’s suggestion to increase the penalties by 25 percent is not consistent with the FCPIAA.

As for the comment’s remarks concerning alleged harm from human drug products, executive compensation, and drug approval, such matters are outside the scope of this rulemaking.

(Comment 2) A comment from the General Accounting Office stated that we had miscalculated the increases for several civil monetary penalties and that the correct amounts should be higher. The comment said that four of the proposed adjustments were not consistent with the law regarding inflation increases and explained that the errors were probably due to applying the specified 10-percent cap before rounding instead of after the prescribed rounding. Thus, because all 14 rounded CPI adjustments exceeded the specified 10-percent cap, each penalty should be increased by exactly 10 percent to be consistent with the FCPIAA.

Consequently, the four civil monetary penalty adjustments, as originally proposed and as revised under the comment’s interpretation of the FCPIAA’s rounding and increase cap formulas, are as follows: