deception or provided the Commission with any market research or other data bearing on how consumers view the various methods of measuring television screens.

When the Commission initially promulgated the Rule in 1966, most television manufacturers measured the dimensions of their television sets diagonally, just as they do today. Thus, the horizontal dimension was not chosen based on a belief that it was the industry norm. Rather, the Commission found that almost all rectangular objects were measured horizontally and vertically. Television screens were the only rectangular-shaped commodities that were measured diagonally. Thus, the Commission reasoned, if a rectangular screen was measured in the usual manner for similarly-shaped objects, then no disclosure was necessary.[10] Moreover, the television industry has adopted the Rule's disclosure requirements as part of its routine business practice, although the industry generally does not use the Rule's default horizontal measurement method. In 1994, the Commission rejected a similar proposal to amend the Rule to adopt the diagonal measurement method as the standard in the Rule (59 FR 54809, 54811 (November 2, 1994)).

The Commission is not aware of any evidence that revising the Rule to require a disclosure when a measurement other than the diagonal dimension is used, or to require marketers to describe screen size in square inches or metric units, would provide a tangible benefit to consumers. Moreover, revising the Rule to make the diagonal measurement the default measurement as CEA proposed could potentially cause confusion to the extent consumers accustomed to seeing screen measurements described as diagonal might mistakenly believe the measurements not described as diagonal are in fact based on horizontal or area measurements. The commenters failed to submit convincing evidence that their proposed changes would confer net benefits on consumers or the industry, or that the Rule as amended would better protect consumers from deception.

The Commission believes that the Rule is sufficiently flexible to allow industry to use the method it prefers for measuring television screen sizes to meet consumer expectations and compete effectively, is easy to comply with at minimal cost, and ensures that advertising contains sufficient information on screen size to allow consumers to make informed purchasing decisions. If marketers determine they can compete more effectively by disclosing screen size measured in square inches or metric units, the Rule allows them to do so. Thus, expending additional resources at this time to seek further comment and testimony at hearings on the methods of measuring television screens is not justified. The absence of evidence indicating a need to amend the Rule and the risk, however small, that amending the Rule as CEA proposed would cause confusion argues against conducting a rulemaking proceeding to re-write the Rule. The Commission has therefore determined not to amend the Rule's disclosure requirements at this time.

C. Suggested Changes to the Rule Regarding Metric Disclosures

Five individual commenters urged the Commission to amend the Rule to require the industry to use metric measurements, in conformance with the Metric Conversion Act.[11] As discussed above, in 1994, the Commission amended the Rule to provide metric equivalents for the measurements stated in inches in the Rule's examples. The Commission noted further that inclusion of metric figures in the Rule was for information purposes only and did not impose a requirement on the industry. In the Commission's view, the Rule is sufficiently flexible to permit industry members to use metric measurements, if they choose to do so to compete effectively in the global marketplace. Accordingly, the Commission has determined not to amend the Rule in this manner.

D. Suggested Changes to the Rule Regarding Rounding

CEA requested that the Commission amend the Rule to address the issue of rounding fractional television screen size dimensions to whole numbers to provide consistency within the industry.[12] In support of its request, CEA referenced an Electronics Industries Alliance (''EIA'') statement that specifies a system for rounding television screen sizes to whole numbers. According to CEA, the statement provides, in part, that, ''A tube having its screen size within plus or minus one-half centimeter shall be assigned that integer. A tube falling exactly on a one-half centimeter shall be assigned the next larger integer.'' [13] CEA recommended that the Commission amend the Rule to adopt an approach to rounding consistent with this statement.

In the absence of consumer research or other evidence on the record in this proceeding that revising the Rule as proposed by CEA would not result in deception in connection with disclosing the viewable picture area of a television screen, the Commission has determined not to amend the Rule at this time to address the issue of rounding.

IV. Conclusion

For the reasons described above, the Commission has determined to retain the current Rule and is terminating this review.

List of Subjects in 16 CFR Part 410

Advertising, Picture tubes, Television sets, Trade practices.

Authority: 15 U.S.C. 41–58.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. E6–9233 Filed 6–13–06; 8:45 am]

BILLING CODE 6750–01–P

[10] 31 FR 3342 (March 3, 1966).

[11] Woelflein at 1; Young at 1; Payne at 1; Hudnall at 1; and Hooper at 1. Under Executive Order 12770 of July 25, 1991 (56 FR 35801), and the Metric Conversion Act, as amended by the Omnibus Trade and Competitiveness Act (15 U.S.C. 205), all Federal agencies are required to use the SI metric system of measurement in all procurements, grants and other business-related activities (which include rulemakings), except to the extent that such use is impractical or is likely to cause significant inefficiencies or loss of markets to United States firms.

[12] CEA at 4.

[13] *See* Worldwide Type Designation System for TV Picture Tubes and Monitor Tubes, ECA–TEP–106B. EIA is a partnership of electronic and high-tech associations and companies whose mission is promoting the market development and competitiveness of the U.S. high-tech industry. EIA's nearly 1,300 member companies represent the full range of consumer electronic products.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 203

[Docket Nos. 1992N–0297 (Formerly 92N–0297), 1988N–0258 (Formerly 88N–0258), 2006D–0226]

Prescription Drug Marketing Act Pedigree Requirements; Effective Date and Compliance Policy Guide; Request for Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; announcement of effective date; notice of availability; request for comment.

SUMMARY: The Food and Drug Administration (FDA) does not intend to further delay the effective date of certain provisions of the final regulation published in the **Federal Register** of

December 3, 1999 (64 FR 67720). The provisions will therefore go into effect on December 1, 2006. In addition, FDA is announcing the availability of a new compliance policy guide (CPG) 160.900 entitled ''Prescription Drug Marketing Act Pedigree Requirements Under 21 CFR Part 203'' for public comment. This CPG describes how the agency intends to prioritize its enforcement efforts during the next year with respect to pedigree requirements set forth in the Federal Food, Drug, and Cosmetic Act (the act) and certain FDA regulations.

DATES: The effective date for §§ 203.3(u) and 203.50 is December 1, 2006. You may submit written or electronic comments on the CPG by July 14, 2006.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent. Submit written comments on the CPG to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the CPG document.

FOR FURTHER INFORMATION CONTACT: Ilisa Bernstein, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360.

SUPPLEMENTARY INFORMATION:

I. Background

A. Implementation of §§ 203.3(u) and 203.50 of 21 CFR Part 203

The Prescription Drug Marketing Act of 1987 (the PDMA), as modified by the Prescription Drug Amendments of 1992, amended sections 301, 303, 503, and 801 of the act (21 U.S.C. 331, 333, 353, 381) to establish, among other things, requirements related to the wholesale distribution of prescription drugs. A primary purpose of the PDMA was to increase safeguards to prevent the introduction and retail sale of substandard, ineffective, and counterfeit drugs in the U.S. drug supply chain.

Section 503(e)(1)(A) of the act establishes the so-called ''pedigree'' requirement for prescription drugs. A drug pedigree is a statement of origin that identifies each prior sale, purchase, or trade of a drug, including the dates of those transactions and the names and addresses of all parties to them. Under the pedigree requirement, each person who is engaged in the wholesale distribution of a prescription drug in interstate commerce, who is not the manufacturer or an authorized distributor of record for that drug, must provide to the person who receives the drug a pedigree for that drug. The PDMA states that an authorized distributor of record is a wholesaler that has an ''ongoing relationship'' with a manufacturer to distribute that manufacturer's drug. However, the PDMA does not define ''ongoing relationship.''

In 1999, FDA published final regulations implementing the PDMA (part 203 (21 CFR part 203)). The regulations were to take effect in December 2000. After publication of the 1999 final rule, the agency received comments objecting to the provisions in §§ 203.3(u) and 203.50. Section 203.3(u) defines ''ongoing relationship'' to include a written agreement between manufacturer and wholesaler. Section 203.50 specifies the fields of information that must be included in the drug pedigree and states that the information must be traceable back to the first sale by the manufacturer. Based on concerns raised by various stakeholders, the agency delayed the effective date of §§ 203.3(u) and 203.50 several times.

Most recently, in February 2004, FDA delayed the effective date of §§ 203.3(u) and 203.50 until December 1, 2006, in part because we were informed by stakeholders in the U.S. drug supply chain that the industry would voluntarily implement electronic track and trace technology by 2007. If widely adopted, this technology could create a de facto electronic pedigree documenting the sale of a drug product from its place of manufacture through the U.S. drug supply chain to the final dispenser. If properly implemented, an electronic record could thus meet the pedigree requirements in section 503(e)(1)(A) of the act. Based on a recent fact-finding effort by FDA to assess the use of e-pedigree across the supply chain, however, it appears that industry will not fully implement track and trace technology by 2007.

Today, the agency is announcing that it does not intend to delay the effective date of §§ 203.3(u) and 203.50 beyond December 1, 2006. As such, these provisions defining ''ongoing relationship'' and setting forth requirements regarding the information that must appear in pedigrees will go into effect as of December 1, 2006.

B. CPG

We are issuing a draft CPG that describes how we plan to prioritize our enforcement actions during the next year with respect to these new requirements. To this end, FDA is announcing the availability of a new CPG Section 160.900, entitled ''Prescription Drug Marketing Act Pedigree Requirements Under 21 CFR Part 203.'' This CPG, which the agency is publishing in draft for comment, lists factors that FDA field personnel are expected to consider in prioritizing FDA's pedigree-related enforcement efforts during the next year. Consistent with our risk-based approach to the regulation of pharmaceuticals, these factors focus our resources on drug products that are most vulnerable to counterfeiting and diversion or that are otherwise involved in illegal activity.

FDA has not provided in the CPG a list of drug products that have been counterfeited in the past. We solicit comment on the merit of providing such a list.

The priorities described in the CPG reflect a phased-in type approach to the enforcement of the stayed pedigree provisions. The CPG will expire 1 year after the final CPG is issued. By providing guidance on the types of drugs that are currently of greatest concern to FDA, we believe that wholesale distributors will have a better idea of where and how to focus their initial energies as they implement systems to come into complete compliance with part 203 for all the prescription drugs they distribute.

FDA is issuing this CPG as a level 1 guidance consistent with FDA's good guidance practices regulations (21 CFR 10.115).

We note that guidance documents are not binding on FDA or industry, and, under appropriate circumstances, the agency may initiate regulatory action, including a criminal prosecution, for pedigree violations that do not meet the factors set forth in the CPG.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the CPG document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

An electronic version of this guidance is available on the Internet at *http://www.fda.gov/ora* under ''Compliance Reference''.

Dated: June 7, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–5362 Filed 6–9–06; 9:35 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 943

[Docket No. TX–054–FOR]

Texas Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSM), are approving an amendment to the Texas regulatory program (Texas program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Texas proposed to revise its fish and wildlife habitat revegetation guidelines by adding technical guidelines and management practices concerning habitat suitable for bobwhite quail and other grassland bird species. Texas intends to revise its program to encourage reclamation practices that are suitable for bobwhite quail and other grassland bird species.

DATES: *Effective Date:* June 14, 2006.

FOR FURTHER INFORMATION CONTACT: Michael C. Wolfrom, Director, Tulsa Field Office. Telephone: (918) 581–6430. E-mail: *mwolfrom@osmre.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the Texas Program
II. Submission of the Amendment
III. OSM's Findings
IV. Summary and Disposition of Comments
V. OSM's Decision
VI. Procedural Determinations

I. Background on the Texas Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, ''a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of this Act * * *; and rules and regulations consistent with regulations issued by the Secretary pursuant to this Act.'' See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Texas program effective February 16, 1980. You can find background information on the Texas program, including the Secretary's findings, the disposition of comments, and the conditions of approval, in the February 27, 1980, **Federal Register** (45 FR 12998). You can find later actions on the Texas program at 30 CFR 943.10, 943.15, and 943.16.

II. Submission of the Amendment

By letter dated July 26, 2005 (Administrative Record No. TX–659), Texas sent us an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*). Texas sent the amendment at its own initiative.

We announced receipt of the proposed amendment in the August 31, 2005, **Federal Register** (70 FR 51689). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the adequacy of the amendment. We did not hold a public hearing or meeting because no one requested one.

During our review of the amendment, we identified concerns relating to Texas' revegetation guidelines document at Section V.D.1., Fish and Wildlife Habitat; Section V.D.2., Woody-Plant Stocking; Appendix B, Summary of Revegetation Success Standards (Fish and Wildlife Habitat Only); and Attachment 2, Minimum Woody Vegetation Stocking Rates. We notified Texas of the concerns by letters dated October 17, 2005, and February 8, 2006 (Administrative Record Nos. TX–659.07 and TX–659.13). On January 12 and March 10, 2006, Texas sent us revisions to its amendment (Administrative Record Nos. TX–659.11 and TX–659.12).

Based on Texas' revisions to its amendment, we reopened the public comment period in the April 21, 2006, **Federal Register** (71 FR 20602). The public comment period ended on May 8, 2006. We received comments from one industrial group, one mining association, one State agency, and one Federal agency.

III. OSM's Findings

Following are the findings we made concerning the amendment under SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17. We are approving the amendment as described below. Any revisions that we do not specifically discuss below concern nonsubstantive wording or editorial changes.

A. Section V. Revegetation Success Standards

At the request of the Texas Parks and Wildlife Department (TPWD), Texas proposed to revise the following provisions in Section V of its August 1999 revegetation success guidelines document.

1. Table of Contents

Texas revised the Table of Contents for Section V.D. Fish and Wildlife by adding two sub-categories entitled ''General Category'' and ''Bobwhite Quail and Other Grassland Bird Species.''

Because these changes are minor, we find that they will not make Texas' revegetation success guidelines document less effective than the corresponding Federal regulation at 30 CFR 816.116(a)(1). This Federal regulation requires that standards for success and statistically valid sampling techniques for measuring success be selected by the regulatory authority and included in an approved regulatory program.

2. Section V.D.1. Fish and Wildlife Habitat—Ground Cover

At Section V.D.1., Texas added a ground cover technical standard for bobwhite quail and other grassland bird species and added other associated changes. Texas also made some minor clarifying changes to existing provisions.

a. Texas changed the heading of the third paragraph from ''Use of Technical Standard'' to ''Use of General Technical Standard.''

Because this change is minor, we find that it will not make Texas' revegetation success guidelines document less effective than the corresponding Federal regulation at 30 CFR 816.116(a)(1).

b. Use of Bobwhite Quail and Other Grassland Bird Species Technical Standard.

(1) Texas proposed to add two new paragraphs concerning the technical standard for bobwhite quail and other grassland bird species. They read as follows:

Use of Bobwhite Quail and Other Grassland Bird Species Technical Standard. The technical standard is 63% to 70% ground cover.

Erosion of landscapes is a natural process dependent on relief, type of geologic material, precipitation, and vegetative cover. Appropriate reclamation land use planning takes these factors into account and will ensure that in all cases ground cover will be adequate to control erosion.