Executive Summary

The Commission is adopting new rule 17f–7 under the Investment Company Act and amendments to rule 17f–5, the rule that governs the custody of the assets of registered management investment companies ("funds") with custodians outside the United States. The new rule and rule amendments will permit funds to maintain their assets in foreign securities depositories based on conditions that reflect the operations and role of these depositories. Depositories are systems for the central handling of securities in which transactions in securities are processed through adjustment of electronic account records rather than delivery of certificates.

The rule and amendments are being adopted today to establish basic standards for foreign depositories that may serve as custodians for funds, and generally require that a fund's contract with its global custodian obligate the custodian to analyze and monitor the custody risks of using a depository, and provide information about the risks to the fund or its adviser, as well as any information regarding material changes in the risks. Unlike amended rule 17f–5, rule 17f–7 does not contain any provisions regarding the delegation of authority under the rule. Decisions to maintain assets with a depository would be made by the fund or its adviser, based upon information provided by the global custodian.

I. Background

Rule 17f–5 was adopted in 1984, and extensively revised in 1997.1

1. Eligible Securities Depository
2. Risk Analysis, Monitoring and Notification
3. Exercise of Care

1 Unless otherwise noted, all references to rules 17f–5, 17f–7, and 7d–1 (or any paragraph of those rules) will be to 17 CFR 270.17f–5, 270.17f–4, and 270.7d–1, as amended by this release.

2 See Exemption for Custody of Investment Company Assets Outside the United States, Investment Company Act Release No. 14132 (Sept. 7, 1984) [49 FR 36080 (Sept. 14, 1984)]. Section 17(f) of the Investment Company Act, which governs fund custody arrangements, does not Amendments") to reflect significant developments in foreign investment by U.S. funds and the Commission's greater experience with foreign custody arrangements. The 1997 Amendments expanded the types of foreign banks and securities depositories that may serve as custodians of fund assets, and required that the selection of a foreign custodian be based on whether the fund's assets will be subject to reasonable care if maintained with that custodian. In 1998, as a result of difficulties experienced by funds, their advisers and bank custodians in applying the standards of rule 17f–5 to the use of foreign depositories, representatives of funds asked the Commission to delay the compliance date for the 1997 Amendments. The Commission suspended the compliance date for most of the 1997 Amendments in May 1998. Representatives of funds and bank custodians then submitted a proposal to further amend rule 17f–5 to change the standards by which foreign depositories are evaluated.

5 The history of rule 17f–5 is discussed in greater detail in the introductory material of the Proposing Release. See proposing Release, supra note 4, at nn.2–17 and accompanying text.
6 See Custody of Investment Company Assets Outside the United States, Investment Company Act Release No. 23701 (May 21, 1998) [63 FR 29345 (May 29, 1998)]. A further extension remains in effect today. See Custody of Investment Company Assets Outside the United States: Extension of Compliance Date, Investment Company Act Release No. 23814 (Apr. 29, 1999) [64 FR 24488 (May 6, 1999)] ("extending compliance date until the Commission acts on 1999 proposals or May 1, 2000"). The compliance date for the amended definition of "eligible foreign custodian" remained June 16, 1998. Compliance with the 1997 Amendments will be measured when amended rule 17f–5 and new rule 17f–7 take effect. See infra notes 38 to 40 and accompanying text (discussing effective date and compliance date for amended rule and new rule; prior to the compliance date, a fund may comply with the 1997 Amendments or follow other compliance options).
7 See Proposing Release, supra note 4, at nn.13 & 15 and accompanying text. The submitted proposal (the "IC/Bank Proposal") would have deemed fund assets maintained with a depository to be subject to reasonable care if a single objective criteria were met. See id. at 16. Under a revised joint proposal submitted in 1999, the foreign custody matter would have (i) considered other information known to it that established certain compliance problems, and (ii) monitored depository arrangements for material changes. See id.
Last year, we proposed amendments to rule 17f–5 and a new rule 17f–7.8 We received letters from seven commenters on the proposals.9 Commenters generally favored the proposals, but also recommended changes.10 We are adopting new rule 17f–7 with modifications that respond to certain of the issues raised by commenters; we are adopting the amendments to rule 17f–5 substantially as proposed.11

II. Discussion

A. Foreign Securities Depositories: Rule 17f–7

New rule 17f–7 permits a fund to maintain assets with a foreign securities depository if certain conditions are met. First, the depository must be an “eligible securities depository” as described below. Second, the fund’s “primary custodian” must provide the fund or its adviser with an analysis of the custodial risks of using the depository, monitor the depository on a continuing basis and notify the fund of any material changes in risks associated with using the depository. The rule defines a primary custodian (often referred to as a “global custodian”) as a U.S. bank or qualified foreign bank (as defined by rule 17f–5) that contracts directly with the fund to provide custodial services for foreign assets.12

1. Eligible Securities Depository

Under the rule, funds and their custodians may maintain their assets with a foreign securities depository only if it is an “Eligible Securities Depository.” An eligible securities depository must act as or operate a system for the central handling of securities that is regulated by a foreign financial regulatory authority.13 In addition, an eligible securities depository must:14

- (Hold assets on behalf of the fund under safekeeping conditions no less favorable than those that apply to other participants;
- [Maintain records that identify the assets of participants, and keep its own assets separated from the assets of participants;]
- [Provide periodic reports to participants; and]
- [Undergo periodic examination by regulatory authorities or independent accountants.]

The proposed rule included within the definition of eligible securities depository certain foreign transfer agents that perform custodial functions analogous to those of a depository.17 Commenters urged that the rule not address these types of arrangements, which are found in countries such as Russia and Ukraine.18

1. Eligible Securities Depository: Rule 17f–7

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continuing basis, and promptly notify the fund or its adviser of any material change. We have written the risk analysis requirements of the rule broadly to provide custodians with flexibility to tailor the risk analysis to the specific risks involved in the use of each particular depository. The rule does not prescribe specific factors or types of risk to be considered in a risk analysis. As a general matter we expect that an analysis will cover a depository’s expertise and market reputation, the quality of its services, its financial strength, any insurance or indemnification arrangements, the extent and quality of regulation and independent examination of the depository, its standing in published ratings, its internal controls and other procedures for safeguarding investments, and any related legal protections.

Rule 17f–7 does not assign a role to the investment adviser or fund board, but is designed to require that sufficient material information about depositories is provided to the fund or adviser in a timely manner. The decision whether to place fund assets with a depository should be made by the adviser (subject to oversight of the fund’s board) or the fund, after consideration of the information provided by the primary custodian or its agent, and based on standards of care that are generally applicable to fund advisers and directors. The decision to place fund assets with a depository does not have to be made separately, but may be made in the overall context of the decision to invest in a particular country.

As proposed, rule 17f–7 would have permitted a fund to rely on indemnification or insurance that adequately protects the fund from all custodial risks of using the depository, as an alternative to the risk analysis and monitoring requirement. Several commenters urged that we not adopt this alternative, and pointed out that, if we did, they would need guidance on the scope and amount of indemnification adequate to meet the requirements of the rule. In light of the issues raised by commenters and the likelihood that this alternative would not be used by funds, we have decided not to adopt it. Instead, as noted above, we suggest that insurance and indemnification arrangements are factors that a risk analysis would cover.

3. Exercise of Care. Rule 17f–7 requires the fund’s contract with its primary custodian to provide that the primary custodian will agree to exercise reasonable care, prudence and diligence in performing its duties under the rule, or adhere to a higher standard of care. This standard of care is the same required of foreign custody managers under rule 17f–5, and is similar to standards for U.S. custodians under commercial law.

B. Foreign Bank Custodians: Rule 17f–5

Amended rule 17f–5 will continue to govern a fund’s use of a foreign bank custodian. As amended, the rule excludes arrangements with foreign securities depositories from its scope because they are addressed by rule 17f–7. The amended rule also reflects other clarifying changes from the previous version of the rule. A note to amended rule 17f–5 (and a similar note to rule 17f–7) explains that when a depository arrangement involves one or more foreign bank custodians through which assets are maintained with the depository, rule 17f–5 applies to the fund’s or its custodian’s use of each foreign bank subcustodian, while rule

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22 See rule 17f–5(a)(1)(i)(B). The proposed rule would have required the primary custodian to “continuously monitor the custody risks or of using a foreign depository. One commenter argued that the term “continuously” could imply that the primary custodian must learn of material changes affecting the depository’s ability to perform its duties quickly or sometimes even before it learns of developments affecting other subcustodians such as a foreign bank. As adopted, rule 17f–7 mirrors a requirement in Rule 17f–5(a)(1)(i) of the United Kingdom that custodians be subject to a “continuing risk assessment.” See United Kingdom Securities and Futures Authority, Board Notice 433, New Safeguarding Rules—Recent Rule 4–107(1).

23 See supra note 4, at nn.38–43 and accompanying text. As with the preparation of the initial risk analysis, a local subcustodian or other intermediary is a pro rata interest shared with other subcustodians, with “due care in accordance with commercial law.”

27 A commenter suggested that a primary custodian should be permitted to suspend its monitoring and notification activities if political developments or other circumstances interfere with these obligations. The Commission anticipates that exceptional developments will be addressed in a report to the fund and that the primary custodian, in performing its duties under the contract, will make a reasonable effort to continue to monitor further developments or to resume monitoring as soon as practicable in these circumstances.

28 One commenter pointed out that certain transactions may perform depository and global custodial functions. Under the rule, the risk analysis of a transnational depository that also performs custodial functions should take into consideration any information reasonably available to the primary custodian from the depository regarding its custodial network (e.g., the local bank subcustodians’ internal controls, financial strength, and information regarding enforceability of judgments). Relevant measures of financial strength might include the level of settlement guarantee funds, collateral requirements, lines of credit, or insurance as compared with participants’ daily settlement obligations.

29 This factor relates to requirements under the definition of an eligible securities depository.
Proposing Release, we requested comments and specific data regarding the costs and benefits of the proposed rule and rule amendments, but commenters did not address any specific costs or quantify any benefits. New rule 17f-7 and the amendments to rule 17f-5 respond to concerns expressed by global custodians and fund managers that rule 17f-5, as amended in 1997, is not workable. The new rule and rule amendments also address our concerns that, as a result of global custodians’ unwillingness to assume delegated responsibilities under rule 17f-5, obligations to evaluate depositories’ custodial capabilities may fall to fund boards, which lack the relevant knowledge and expertise to make these evaluations.

We believe that new rule 17f-7 will benefit investors by establishing a workable framework under which assets may be maintained in foreign depositories consistent with the investor protection goals of the Investment Company Act. Under this rule, we recognize that investment in many foreign countries presents custodial risks that cannot be avoided, including the use of local securities depositories. The rule seeks to reduce the risks by requiring that fund advisers (or funds) be fully apprised of these risks when they make the decision to invest in the country on an ongoing basis. The rule will also benefit funds and their shareholders by freeing fund boards of the responsibility to make findings concerning foreign depositories that often remained with them after the 1997 Amendments because of global custodians’ refusals to accept delegated responsibility. As a result, fund boards should have more time to address other issues that are important to investors.

New rule 17f-7 and the amendments to rule 17f-5 may impose costs. Although the new rule sets minimum requirements for depositories, it does not dictate a standard for custody risks. A depository may fail, causing losses to investors, despite the diligence of global custodians, funds and advisers. Global custodians should not incur materially greater costs under new rule 17f-7, which generally requires them to perform duties they may perform already under custodial contracts. Rule 17f-7 may have the effect of requiring global custodians to exercise a greater degree of vigilance in monitoring depositories (or to refrain in the future from reducing their diligence) because it requires them to monitor a depository “on a continuing basis,” and in this respect may impose some costs. It is unlikely, however, that these costs will be material, since many custodians already monitor their foreign subcustodians, the countries in which these subcustodians are located, and foreign securities depositories. Existing custodial agreements with funds may need to be amended because of rule 17f-7 and the amendments to rule 17f-5. We expect that global custodians may pass on additional costs to mutual funds, but that the costs are unlikely to materially affect overall fund expense ratios, in part because custodial fees are not calculated on an hourly basis.

The Commission staff estimates that approximately 3,690 fund portfolios will be affected by rule 17f-7 and the amendments to rule 17f-5. The staff estimates that during the first year after rule 17f-7 goes into effect, approximately 15 global custodians (or their agents) will make an average of 80 responses per custodian, and that each response will require approximately 10 hours, for a total annual burden for global custodians of 12,000 hours. The staff estimates that during the first year after the amendments to rule 17f-5 go into effect, approximately 15 global custodians will be required to make an average of 80 responses per custodian concerning the use of foreign custodians other than depositories, requiring 10 hours per response. In addition, during that first year, the staff estimates that each custodian will require approximately 96 hours for an additional “response” under rule 17f-5, which involves renegotiating the custodial contract with the fund and establishing a system to monitor custody arrangements for the fund. The total annual burden associated with the amendments to rule C. Conforming Amendments

Conforming amendments to rules 17f-4 and 7d-1 clarify references to rule 17f-5 by adding a reference to rule 17f-7. One commenter recommended that the word “foreign” be deleted from the reference to a “foreign eligible securities depository” in the proposed amendment to rule 17f-4 because it is too restrictive. As adopted, the amendment to rule 17f-4 does not delete the word “foreign,” and refers instead to an “eligible securities depository” as defined in new rule 17f-7.

III. Effective Date

New rule 17f-7 and the amendments to rule 17f-5 will be effective June 12, 2000. Compliance with the new rule and rule amendments will not be required until July 2, 2001. In the interim, a fund may operate its foreign custody arrangements in accordance with the new rule and amendments or with the 1997 Amendments to rule 17f-5, or it may comply with “old” rule 17f-5 as it existed prior to the 1997 Amendments (but subject to the definition of an eligible foreign custodian under the 1997 Amendments).

IV. Cost-Benefit Analysis

The Commission is sensitive to the costs and benefits of its rules. In the

36 See Note to amended rule 17f-5; Note to rule 17f-7.

37 This change clarifies that an eligible securities depository may include, for example, a branch of a U.S. bank that meets the other requirements of the definition of an eligible securities depository.

38 A fund may undertake to comply with new rule 17f-7 and amended rule 17f-5 before the compliance date. With respect to fund assets in the custody of a foreign securities depository before it has begun to comply with rule 17f-7, we expect the fund or its adviser to determine whether the depository is an eligible securities depository as defined by the rule, and to obtain an initial risk analysis of the depository by the compliance date.

39 Compliance with the 1997 Amendments will become moot when amended rule 17f-5 and new rule 17f-7 take effect. See supra note 6 (clarifying the status of the compliance date for the 1997 Amendments). Therefore, the Commission is extending the compliance date of the 1997 Amendments to the effective date of the rule and amendments we are adopting today.

40 See Custody of Investment Company Assets Outside the United States, Investment Company Act Release No. 23201 (May 21, 1998) [63 FR 29345, May 29, 1998] at nn.7 & 9 and accompanying text. The fund may apply any of these alternative frameworks separately to each foreign custodian or subcustodian it uses. The fund’s arrangement with a particular foreign custodian, subcustodian, or depository should comply in its entirety with amended rule 17f-5 and new rule 17f-7, or with rule 17f-5 as amended by the 1997 Amendments, or with old rule 17f-5 as it existed prior to the 1997 Amendments (but subject to the amended definition of an eligible foreign custodian).

41 Rule 17f-7 should not materially increase a custodian’s risk of liability because most custodial contracts will probably continue to limit the custodian’s liability, particularly with respect to information it may receive from third parties.

42 This information is based on data reported by funds on Form N-SAR [17 CFR 274.101].

43 These estimates assume that each of the 15 custodians services an average of 250 client portfolios within 40 fund complexes, that a single response by each custodian can simultaneously address approximately 6 client portfolios in a fund complex. A “response” may involve the preparation of risk analyses of depository arrangements, the monitoring of depositories for material changes in risks and the preparation of notices for funds of material changes in risks related to these depositories.

44 These estimates assume that each custodian will require approximately 96 hours for an additional “response” under rule 17f-5, which involves renegotiating the custodial contract with the fund and establishing a system to monitor custody arrangements for the fund. The total annual burden associated with the amendments to rule 17f-7 applies to the subcustodian’s use of the depository itself.
17f–5 for global custodians during the first year will be approximately 13,440 hours (15 global custodians × 896 hours per global custodian).

Under rule 17f–7, funds or their advisers will bear the cost of evaluating the information provided by global custodians and making decisions regarding the continued use of a depository (and in this respect, continued investment in the country where the depository is located). We believe that in the context of foreign depository arrangements, this allocation of costs is appropriate in light of (i) the unwillingness of global custodians to assume responsibilities that may overlap with investment decisions and (ii) the extent to which the decision to use a foreign depository may affect an investment strategy that contemplates investment in a particular foreign market. An adviser’s costs (and the related fund’s costs) should not materially increase because of the rule, since decisions concerning use of a depository likely are part of the overall decision to invest in a country, and are decisions that funds and their advisers made prior to adoption of rule 17f–7.

Savings under rule 17f–5 may offset increased costs to funds and their advisers with respect to new rule 17f–7, since fund directors will no longer have to make time-consuming “reasonable care” determinations regarding foreign depositories.

The staff estimates that during at least the first year after rule 17f–7 goes into effect, approximately 650 investment advisers will make an average of 3 responses per adviser under the new rule, requiring a total of approximately 25 hours for each adviser.\(^{47}\) The total annual burden for funds and their advisers under rule 17f–7 will be approximately 16,250 hours. The staff further estimates that during the first year after the amendments to rule 17f–5 go into effect, the total annual burden associated with the rule’s requirements will be approximately 7,380 hours (3,690 portfolios × 2 hours per portfolio).\(^{48}\) The removal of custody arrangements involving securities depositories from amended rule 17f–5 may eliminate as many as 28,600 burden hours from the current total burden hours for funds and their advisers.\(^{49}\)

It is unclear whether the new rule and rule amendments will increase or decrease investments in funds holding foreign securities. Custody risks are only one factor investors may consider before deciding to invest in a particular fund. Fund managers may have more information regarding custodial risks because of the new rule and amendments, and this may affect their decisions regarding where to invest a fund’s assets, or in some cases, when to remove a fund’s assets from a country. The new rule and rule amendments may affect competition among custodians, but are unlikely to significantly change the tasks that custodians currently perform. The rules allow third parties to prepare risk analyses and monitor depositories for changes in risks for custodians. It is unclear whether custodians will pass the costs of utilizing these third party service providers to funds or investors. Many custodians already may be using the services of these providers.

V. Effects on Efficiency, Competition and Capital Formation

Section 2(c) of the Investment Company Act requires the Commission, when engaging in rulemaking that requires it to consider or determine whether an action is consistent with the public interest, to consider whether the action will promote efficiency, competition and capital formation.\(^{50}\) The Commission has considered these factors.

As discussed above, the Commission anticipates that new rule 17f–7 and the amendments to rule 17f–5 will provide a workable framework under which a fund can protect its assets while maintaining them with a foreign securities depository. These rule changes may marginally promote efficiency in custody arrangements involving foreign assets by better delineating the responsibilities of fund boards, fund advisers and custodians with respect to custody of investment company assets outside the United States, whether an eligible foreign custodian or an eligible securities depository holds them. It is unlikely that the rule changes will have any material effect on competition among custodians, because the rules do not substantially change the duties of custodians, or increase the potential universe of custodians or depositories. The rule changes should also have little effect on domestic capital formation because the rules relate only to foreign custody of fund assets. There are relatively few funds affected by the new rules and amendments, compared to the total number of funds. Similarly, the total dollar amount invested in funds affected by the rule and amendments is also relatively small, compared to the total amount invested in all funds.

VI. Paperwork Reduction Act

Certain provisions of new rule 17f–7 and the amendments to rule 17f–5 contain “collection of information” requirements within the meaning of the Paperwork Reduction Act of 1995.\(^{51}\) The Commission submitted the collection of information requirements contained in the rule and rule amendments to the Office of Management and Budget (“OMB”) for review in accordance with 44 U.S.C. 3507(d) and 5 CFR 1320.11.\(^{52}\) An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the agency displays a valid OMB control number.\(^{53}\)

A. New Rule 17f–7

New rule 17f–7 contains some collection of information requirements. Under the rule, an eligible securities depository must meet certain minimum standards. The fund or its investment...
adviser will generally determine whether the depository complies with those requirements based on information provided by the fund’s primary custodian. The depository custody arrangement also must meet certain conditions. The fund or its adviser must receive from the primary custodian (or its agent) an initial risk analysis of the depository arrangements, and the fund’s contract with its primary custodian must state that the custodian will monitor risks and promptly notify the fund or its adviser of material changes in risks. The primary custodian and other custodians also must agree to exercise reasonable care.

The staff estimates that during the first year after rule 17f–7 goes into effect, approximately 650 investment advisers will review an average of 3 risk analyses per adviser under the rule, requiring a total of approximately 25 hours for each adviser. Each of these “responses” by an adviser may address depository compliance with the minimum requirements of the rule, and require the adviser to review risk analyses or notifications of material changes in risks related to a depository.54 The total annual burden associated with these requirements of the rule during the first year is estimated to be approximately 16,250 hours (650 advisers × 25 hours per adviser). The staff further estimates that during the first year after the proposed rule goes into effect, approximately 15 global custodians will make an average of 80 responses per custodian under the rule (80 responses = approximately 10 hours per response).55 A “response” by a global custodian may involve the preparation of the risk analysis, the monitoring of depository risks or the preparation of subsequent notifications of material changes in depositary risks. The total annual burden associated with these requirements of the new rule is estimated to be approximately 12,000 hours (15 custodians × 800 hours). Therefore, the total annual burden associated with all collection of information requirements of new rule 17f–7 during the first year after its adoption is estimated to be 28,250 hours (16,250 + 12,000).

B. Amendments to Rule 17f–5

The amendments to rule 17f–5 do not substantively change the rule’s collection of information requirements, which will continue to apply when a fund (i.e., a registered management investment company) maintains its assets with a foreign bank custodian. The amendments remove custody arrangements with foreign securities depositories from the rule, however, so that the rule’s requirements no longer apply to these custody arrangements. In general, therefore, the amendments reduce the information collection burdens of rule 17f–5.

The requirements of amended rule 17f–5 that may call for the collection of information are substantially the same as under the current rule. The fund’s board of directors must find that it is reasonable to rely on each delegate it selects to act as the fund’s foreign custody manager. The delegate must agree to provide written reports that notify the board when the fund’s assets are placed with a foreign custodian and when any material change occurs in the fund’s custody arrangements. The delegate must agree to exercise reasonable care, prudence, and diligence, or to adhere to a higher standard of care. When the foreign custody manager selects an eligible foreign custodian, it must determine that the fund’s assets will be subject to reasonable care if maintained with that custodian, and that the written contract that governs each custody arrangement will provide reasonable care for fund assets. The contract must contain certain specified provisions or others that provide at least equivalent care. The foreign custody manager must establish a system to monitor the contract and the appropriateness of continuing to maintain assets with the eligible foreign custodian.

The Commission’s staff estimates that during the first year after the amendments go into effect, approximately 3,690 fund portfolios56 will be required to make an average of one response per portfolio under amended rule 17f–5, requiring approximately 2 hours of director time per response, to make the necessary findings concerning foreign custody managers.57 A “response” by a fund portfolio may involve the directors making certain findings concerning foreign custody managers, and the review and ratification of custodial contracts. The total annual burden associated with these requirements of the amended rule during the first year is estimated to be approximately 7,380 hours (3,690 portfolios × 2 hours per portfolio). The staff further estimates that during the first year after the amended rule goes into effect, approximately 15 global custodians58 will be required to make an average of 80 responses per custodian concerning the use of foreign custodians other than depositories, requiring approximately 10 hours per response, plus one additional response per custodian that requires approximately 96 hours per response.59 A “response” by a custodian under the amended rule may involve negotiating new custodial contracts with funds, establishing bank custody arrangements for fund complexes, preparing reports for funds and establishing a system to monitor custody arrangements. The total annual burden associated with these requirements of the rule during the first year is estimated to be approximately 13,440 hours (15 global custodians × 896 hours per global custodian). Therefore, the total burden of all collection of information requirements of rule 17f–5 during the first year after its amendment is estimated to be approximately 20,820 hours (7,380 + 13,440).60

54 These estimates assume that one adviser manages 6 portfolios, and that each adviser will make 3 responses annually requiring a total of 25 hours for each adviser to address depository compliance with minimum requirements, and reviews of risk analyses or notifications for the adviser’s fund complex. The 25 hours would include 5 hours spent to verify depository compliance with minimum requirements, and 20 hours spent to review risk analyses or notifications for the fund complex.

55 These estimates assume that each of 15 custodians services an average of 250 client portfolios within 40 fund complexes, that a single response by each custodian can simultaneously address approximately 6 client portfolios in a fund complex, and that each custodian makes approximately 80 annual responses requiring 10 hours per response to prepare risk analyses of depository arrangements and monitor risks, and to provide notices of material changes in risks to its clients.

56 This information is based on data reported by funds on Form N-SAR [17 CFR 274.101].

57 The staff estimates that these 3,690 portfolios are divided among approximately 1,327 registered funds within approximately 650 fund complexes that may share the same investment adviser, board of directors, U.S. bank custodian, or all of these entities. Each board of directors and its delegates for a fund complex could therefore meet rule 17f–5’s requirements by simultaneously approving similar arrangements for some 6 portfolios in the same complex. The estimated hour amounts are based on discussions with representatives of funds about the burdens of analogous requirements in another custody rule.

58 This estimate is based on staff review of custody contracts and other research.

59 These estimates assume that each of 15 custodians services an average of 250 client portfolios within 40 fund complexes, that a single response by each custodian can simultaneously address approximately 6 client portfolios in a fund complex, and that each custodian makes approximately 80 responses annually requiring 10 hours per response to establish bank custody arrangements for approximately 40 fund complexes and report to their fund boards, and one response annually requiring 96 hours per response to establish a system to monitor custody arrangements for these clients.

60 The number of responses may decline substantially after the first year because some responses made during that year (e.g., negotiating a custodial contract with a fund or establishing a...
The staff estimates that the amendments’ removal of custody arrangements involving securities depositories from rule 17f–5 will eliminate as much as 28,600 additional burden hours currently imposed by the rule’s collection of information requirements. This estimate assumes that without the amendments, approximately 650 investment advisers would have to make an average of 3 responses per adviser annually (i.e., making reasonable care determinations), requiring a total of approximately 44 hours for each adviser, to address depository arrangements.62 As reflected in the following summary of the burden hours associated with the collection of information requirements in old rule 17f–5, rule 17f–5 as amended, and new rule 17f–7, the staff estimates that the net effect of the new rule and rule amendments will be to reduce the total annual paperwork burden by 350 hours:

<table>
<thead>
<tr>
<th>Rule</th>
<th>Paperwork burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Old rule 17f–5</td>
<td>49,420 hours.</td>
</tr>
<tr>
<td>Rule 17f–5 as amended</td>
<td>20,820 hours.</td>
</tr>
<tr>
<td>New rule 17f–7</td>
<td>28,250 hours.</td>
</tr>
<tr>
<td>Net reduction</td>
<td>350 hours.</td>
</tr>
</tbody>
</table>

The information collection requirements imposed by the new rule and rule amendments are required for those funds that decide to rely on the rules to obtain the benefit of maintaining assets in foreign custody arrangements. Funds that do not maintain assets in foreign custody arrangements are not required to rely on the rules. Responses to the collections of information will not be kept confidential.

VII. Summary of Final Regulatory Flexibility Analysis

The Commission has prepared a Final Regulatory Flexibility Analysis (“FRFA”) in accordance with 5 U.S.C. 604 relating to new rule 17f–7, the amendments to rule 17f–5, and the conforming amendments to rules 7d–1 and 17f–4. A summary of the Initial Regulatory Flexibility Analysis (“IRFA”), which was prepared in accordance with 5 U.S.C. 603, was published in the Proposing Release. The following is a summary of the FRFA.

A. Need for and Objectives of the Rule and Rule Amendments

Rule 17f–5 governs the custody of the assets of registered management investment companies (“funds”) with custodians outside the United States. The Commission amended the rule in 1997 to modernize its conditions. In 1998, representatives of funds and bank custodians informed the Commission that some conditions of the rule presented problems regarding the use of foreign securities depositories.

The Commission is adopting new rule 17f–7 and amendments to rule 17f–5, pursuant to the authority set forth in sections 6(c), 7(d), 17(f), and 38(a) of the Investment Company Act [15 U.S.C. 80a–6(c), –7(d), –17(f), and –38(a)], to permit funds to maintain their assets in foreign securities depositories based on conditions that reflect the operations and role of these depositories. New rule 17f–7 establishes new provisions for the use of depositories. The rule requires every foreign securities depository that holds fund assets to meet specified minimum standards. The rule also requires a custody arrangement with a depository to meet certain risk-limiting conditions. The fund or its adviser must receive an initial risk analysis of the depository arrangement from the primary custodian (or its agent), and the fund’s contract with its primary custodian must state that the custodian will monitor those risks and notify the fund or its adviser of material changes in the risks. The primary custodian and other custodians involved in the depository arrangement also must agree to exercise reasonable care.

The amendments to rule 17f–5 remove custody arrangements with foreign securities depositories from the rule. This eliminates the applicability to depository arrangements of requirements that certain findings be made by the fund board, its investment adviser or global custodian, and that certain specified terms or equivalent protections appear in the rules of the depository. The conforming amendments to rules 7d–1 and 17f–4 clarify references to rule 17f–5 by adding a reference to rule 17f–7 as well.

B. Significant Issues Raised by Public Comments

The Commission received no public comments on the IRFA.

C. Small Entities Subject to the Rules

The new rule and rule amendments affect, among other persons, the approximately 15 global custodians that act as foreign custody managers for funds under rule 17f–5 and as primary custodians under rule 17f–7. None of these global custodians likely qualifies as a small entity, because each custodian is a major bank with a global branch network or global ties to other banks.63 The new rule and rule amendments also affect the funds that invest in foreign markets and their investment advisers. Few if any of the affected funds and advisers are small entities.64 On balance, the impact of the new rule and rule amendments on global custodians, funds, and advisers is not expected to be great, because the burdens of the new rule’s requirements will be offset in part by the elimination of burdens by amended rule 17f–5. For this reason, and because few if any of the affected entities would qualify as small entities, the new rule and rule amendments are unlikely to have a significant impact on a substantial number of small entities.

D. Projected Reporting, Recordkeeping, and Other Compliance Requirements

New rule 17f–7 establishes new requirements for arrangements with depositories. As described above, the new rule requires each foreign securities depository that holds fund assets to meet specified minimum requirements. Depository arrangements also must meet other risk-limiting conditions. The fund or its adviser must receive an initial risk analysis of the depository arrangement from the primary custodian (or its agent), and the fund’s contract with its primary custodian must state that the custodian will monitor the risks and promptly notify the fund of any material changes in the risks. The primary custodian and other custodians also must agree to exercise reasonable care.

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62 A fund is considered a small entity if it, together with other investment companies in the same group of related investment companies, has net assets of $50 million or less. See 17 CFR 270.10–10. An adviser is considered a small entity if it has assets under management of less than $25 million, has total assets of less than $5 million, and is not in a control relationship with other advisers or persons that are not small entities. See 17 CFR 275.6. Most funds that invest in foreign securities are part of a fund complex that holds net assets of more than $50 million, and are advised by advisers with assets under management of $25 million or more.

63 A bank is considered by the Small Business Administration to be a small entity if it has less than $100 million in assets. See 13 CFR 121.201 (1999). See also 5 USC 601(3). A bank’s assets are determined by averaging its total assets reported for each of the last four quarters. See 13 CFR 121.201 at n.7.

64 A fund is considered a small entity if it, together with other investment companies in the same group of related investment companies, has net assets of $50 million or less. See 17 CFR 270.10–10. An adviser is considered a small entity if it has assets under management of less than $25 million, has total assets of less than $5 million, and is not in a control relationship with other advisers or persons that are not small entities. See 17 CFR 275.6. Most funds that invest in foreign securities are part of a fund complex that holds net assets of more than $50 million, and are advised by advisers with assets under management of $25 million or more.
The amendments to rule 17f–5 retain existing reporting, recordkeeping, and other compliance requirements of the rule without substantive changes, insofar as they apply to custody arrangements with a foreign bank custodian. The amendments would remove a custody arrangement with a foreign depository from the rule, eliminating the necessity for compliance with the rule’s requirements in these arrangements.

E. Agency Action To Minimize Effects on Small Entities

The Regulatory Flexibility Act directs the Commission to consider significant alternatives that would accomplish the stated objective, while minimizing any significant economic impact on small entities. In considering adoption of the new rule and amendments, the Commission considered: (i) establishing different compliance or reporting standards that take into account the resources available to small entities; (ii) clarifying, consolidating or simplifying the compliance requirements for small entities; (iii) using performance rather than design standards; and (iv) exempting small entities from coverage of all or part of the rule.

We believe that further clarification, consolidation, or simplification of the compliance requirements is not necessary. In addition, performance standards are impracticable with respect to the amendments and new rule. The Commission believes that different requirements for small entities would also be inconsistent with the protection of investors, particularly in light of the fact that rule 17f–7 establishes only minimum requirements for foreign securities depositories.

As discussed above, none of the global custodians affected by new rule 17f–7 or the amendments to rule 17f–5 and few, if any, of the affected funds and advisers are likely to be considered small entities for purposes of the Regulatory Flexibility Act. As further discussed above, the impact of the amendments is likely to be limited, because burdens under the new rule will be offset in part by reduced burdens by amended rule 17f–5. Therefore, the potential impact of the new rule and rule amendments on small entities will not be significant.

The FRFA is available for public inspection in File No. S7–15–99, and a copy may be obtained by contacting Jaea F. Hahn, Attorney, at (202) 942–0690, Office of Regulatory Policy, Division of Investment Management, Securities and Exchange Commission, 450 5th Street, NW, Washington, DC 20549–0506.

VIII. Statutory Authority

The Commission is adopting new rule 17f–7, amending rule 17f–5, and adopting conforming amendments to rules 7d–1 and 17f–4 pursuant to authority set forth in sections 6(c), 7(d), 17(f), and 38(a) of the Investment Company Act [15 U.S.C. 80a–6(c), 80a–7(d), 80a–17(f) and 80a–37(a)].

List of Subjects in 17 CFR Part 270

Investment companies, Reporting and recordkeeping requirements, Securities.

Text of Rules

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

PART 270—RULES AND REGULATIONS, INVESTMENT COMPANY ACT OF 1940

1. The authority citation for part 270 continues to read in part as follows:

Authority: 15 U.S.C. 80a–1 et seq., 80a–34(d), 80a–37. 80a–39 unless otherwise noted:

* * * * *

2. Section 270.7d–1 is amended by revising the introductory text of paragraph (b)(8)(v) to read as follows:

§ 270.7d–1 Specification of conditions and arrangements for Canadian management investment companies requesting order permitting registration.

* * * * *

(b) * * *

(8) * * *

(v) Except as provided in § 270.17f–5 and § 270.17f–7, applicant will appoint, by contract, a bank, as defined in section 2(a)(5) of the Act (15 U.S.C. 80a–2(a)(5)) and having the qualification described in section 26(a)(1) of the Act (15 U.S.C. 80a–26(a)(1)), to act as trustee of, and maintain in its sole custody in the United States, all of applicant’s securities and cash, other than cash necessary to meet applicant’s current administrative expenses. The contract will provide, inter alia, that the custodian will:

* * * * *

3. Section 270.17f–4 is amended by revising the introductory text of paragraph (b) to read as follows:

§ 270.17f–4 Deposits of securities in securities depositories.

* * * * *

(b) A registered management investment company (investment company) or any qualified custodian may deposit all or any part of the securities owned by the investment company in an Eligible Securities Depository as defined in § 270.17f–7 in accordance with the provisions of § 270.17f–7 and applicable provisions of § 270.17f–5, or in:

* * * * *

4. Section 270.17f–5 is revised to read as follows:

§ 270.17f–5 Custody of investment company assets outside the United States.

(a) Definitions. For purposes of this section:

(1) Eligible Foreign Custodian means an entity that is incorporated or organized under the laws of a country other than the United States and that is a Qualified Foreign Bank or a majority-owned direct or indirect subsidiary of a U.S. Bank or bank-holding company.

(2) Foreign Assets means any investments (including foreign currencies) for which the primary market is outside the United States, and any cash and cash equivalents that are reasonably necessary to effect the Fund’s transactions in those investments.

(3) Foreign Custody Manager means a Fund’s or a Registered Canadian Fund’s board of directors or any person serving as the board’s delegate under paragraphs (b) or (d) of this section.

(4) Fund means a management investment company registered under the Act (15 U.S.C. 80a) and incorporated or organized under the laws of the United States or of a state.

(5) Qualified Foreign Bank means a banking institution or trust company, incorporated or organized under the laws of a country other than the United States, that is regulated as such by the country’s government or an agency of the country’s government.

(6) Registered Canadian Fund means a management investment company incorporated or organized under the laws of Canada and registered under the Act pursuant to the conditions of § 270.7d–1.

(7) U.S. Bank means an entity that is:

(i) A banking institution organized under the laws of the United States;

(ii) A member bank of the Federal Reserve System;

(iii) Any other banking institution or trust company organized under the laws of any state or of the United States, whether incorporated or not, doing business under the laws of any state or of the United States, a substantial portion of the business of which consists of receiving deposits or exercising fiduciary powers similar to those permitted to national banks under the authority of the Comptroller of the Currency, and which is supervised and examined by state or federal authority having supervision over banks, and
which is not operated for the purpose of evading the provisions of this section; or
(iv) A receiver, conservator, or other
liquidating agent of any institution or
firm included in paragraphs (a)(7)(i),
(ii), or (iii) of this section.
(b) Delegation. A Fund’s board of
directors may delegate to the Fund’s
investment adviser or officers or to a
U.S. Bank or to a Qualified Foreign
Bank the responsibilities set forth in
paragraphs (c)(1), (c)(2), or (c)(3) of this
section, provided that:
(1) Reasonable Retention. The board
determines that it is reasonable to rely
on the delegate to perform the delegated
responsibilities;
(2) Reporting. The board requires the
delegate to provide written reports
notifying the board of the placement of
Foreign Assets with a particular
custodian and of any material change in
the Fund’s foreign custody
arrangements, with the reports to be
provided to the board at such times as
the board deems reasonable and
appropriate based on the circumstances
of the Fund’s arrangements; and
(3) Exercise of Care. The delegate
agrees to exercise reasonable care,
prudence and diligence such as a person
having responsibility for the safekeeping
of the Fund’s Foreign Assets would
exercise, or to adhere to a higher
standard of care, in performing the
delegated responsibilities.

c) Maintaining Assets with an
Eligible Foreign Custodian. A Fund or
its Foreign Custody Manager may place
and maintain the Fund’s Foreign Assets
in the care of an Eligible Foreign
Custodian, provided that:
(1) General Standard. The Foreign
Custody Manager determines that the
Foreign Assets will be subject to
reasonable care, based on the standards
applicable to custodians in the relevant
market, if maintained with the Eligible
Foreign Custodian, after considering all
factors relevant to the safekeeping of the
Foreign Assets, including, without
limitation:
(i) The Eligible Foreign Custodian’s
practices, procedures, and internal
controls, including, but not limited to,
the physical protections available for
certificated securities (if applicable),
the method of keeping custodial records,
and the security and data protection
practices;
(ii) Whether the Eligible Foreign
Custodian has the requisite financial
strength to provide reasonable care for
Foreign Assets;
(iii) The Eligible Foreign Custodian’s
general reputation and standing; and
(iv) Whether the Fund will have
jurisdiction over and be able to enforce
judgments against the Eligible Foreign
Custodian, such as by virtue of the
existence of offices in the United States
or consent to service of process in the
United States.
(2) Contract. The arrangement with
the Eligible Foreign Custodian is
governed by a written contract that the
Foreign Custody Manager has
determined will provide reasonable care
for Foreign Assets based on the
standards specified in paragraph (c)(1)
of this section.
(i) The contract must provide:
(A) For indemnification or insurance
arrangements (or any combination) that
will adequately protect the Fund against
the risk of loss of Foreign Assets held
in accordance with the contract;
(B) That the Foreign Assets will not be
subject to any right, charge, security
interest, lien or claim of any kind in
favor of the Eligible Foreign Custodian
or its creditors, except a claim of
payment for their safe custody or
administration or, in the case of cash
deposits, liens or rights in favor of
creditors of the custodian arising under
bankruptcy, insolvency, or similar laws;
(C) That beneficial ownership of the
Foreign Assets will be freely
transferable without the payment of
money or value other than for safe
custody or administration;
(D) That adequate records will be
maintained identifying the Foreign
Assets as belonging to the Fund or as
being held by a third party for the
benefit of the Fund;
(E) That the Fund’s independent
public accountants will be given access
to those records or confirmation of the
contents of those records; and
(F) That the Fund will receive
periodic reports with respect to the
safekeeping of the Foreign Assets,
including, but not limited to,
notification of any transfer to or from
the Fund’s account or a third party
account containing assets held for the
benefit of the Fund.
(ii) The contract may contain, in lieu
of any or all of the provisions specified
in paragraph (c)(2)(i) of this section,
other provisions that the Foreign
Custody Manager determines will
provide, in their entirety, the same or a
greater level of care and protection for
the Foreign Assets as the specified
provisions, in their entirety.
(3)(i) Monitoring the Foreign Custody
Arrangements. The Foreign Custody
Manager has established a system to
monitor the appropriateness of
maintaining the Foreign Assets with a
particular custodian under paragraph
(c)(1) of this section, and to monitor
performance of the contract under
paragraph (c)(2) of this section.
(iii) If an arrangement with an Eligible
Foreign Custodian no longer meets the
requirements of this section, the Fund
must withdraw the Foreign Assets from
the Eligible Foreign Custodian as soon
as reasonably practicable.
(d) Registered Canadian Funds. Any
Registered Canadian Fund may place
and maintain its Foreign Assets outside
the United States in accordance with the
requirements of this section, provided
that:
(1) The Foreign Assets are placed in
the care of an overseas branch of a U.S.
Bank that has aggregate capital, surplus,
and undivided profits of a specified
amount, which must not be less than
$500,000; and
(2) The Foreign Custody Manager is
the Fund’s board of directors, its
investment adviser or officers, or a U.S.
Bank.

Note to §270.17f-7: When a Fund’s (or its
custodian’s) custody arrangement with an
Eligible Securities Depository (as defined in
§270.17f–7) involves one or more Eligible
Foreign Custodians through which assets are
maintained with the Eligible Securities
Depository, §270.17f–5 will govern the
Fund’s (or its custodian’s) use of each
Eligible Foreign Custodian, while §270.17f–7
will govern an Eligible Foreign Custodian’s
use of the Eligible Securities Depository.

5. Section 270.17f–7 is added to read as
follows:

§270.17f–7 Custody of investment
company assets with a foreign securities
depository.

(a) Custody arrangement with an
eligible securities depository. A Fund,
including a Registered Canadian Fund,
may place and maintain its Foreign
Assets with an Eligible Securities
Depository, provided that:

(1) Risk-limiting safeguards. The
custody arrangement provides
reasonable safeguards against the
custody risks associated with
maintaining assets with the Eligible
Securities Depository, including:

(i) Risk analysis and monitoring. (A)
The fund or its investment adviser has
received from the Primary Custodian (or
its agent) an analysis of the custody
risks associated with maintaining assets
with the Eligible Securities Depository;
and

(B) The contract between the Fund
and the Primary Custodian requires the
Primary Custodian (or its agent) to
monitor the custody risks associated with
maintaining assets with the
Eligible Securities Depository on a
continuing basis, and promptly notify
the Fund or its investment adviser of
any material change in these risks.

(ii) Exercise of care. The contract
between the Fund and the Primary
Custodian states that the Primary Custodian will agree to exercise reasonable care, prudence, and diligence in performing the requirements of paragraphs (a)(1)(i)(A) and (B) of this section, or adhere to a higher standard of care.

(2) Withdrawal of assets from eligible securities depository. If a custody arrangement with an Eligible Securities Depository no longer meets the requirements of this section, the Fund’s Foreign Assets must be withdrawn from the depository as soon as reasonably practicable.

(b) Definitions. The terms Foreign Assets, Fund, Qualified Foreign Bank, Registered Canadian Fund, and U.S. Bank have the same meanings as in § 270.17f–5. In addition:

(1) Eligible Securities Depository means a system for the central handling of securities as defined in § 270.17f–4 that:

(i) Acts as or operates a system for the central handling of securities or equivalent book-entries in the country where it is incorporated, or a transnational system for the central handling of securities or equivalent book-entries;

(ii) Is regulated by a foreign financial regulatory authority as defined under section 2(a)(50) of the Act (15 U.S.C. 80a–2(a)(50));

(iii) Holds assets for the custodian that participates in the system on behalf of the Fund under safekeeping conditions no less favorable than the conditions that apply to other participants;

(iv) Maintains records that identify the assets of each participant and segregate the system’s own assets from the assets of participating parties;

(v) Provides periodic reports to its participants with respect to its safekeeping of assets, including notices of transfers to or from any participant’s account; and

(vi) Is subject to periodic examination by regulatory authorities or independent accountants.

(2) Primary Custodian means a U.S. Bank or Qualified Foreign Bank that contracts directly with a Fund to provide custodial services related to maintaining the Fund’s assets outside the United States.

Note to § 270.17f–7: When a Fund’s (or its custodian’s) custody arrangement with an Eligible Securities Depository involves one or more Eligible Foreign Custodians (as defined in § 270.17f–5) through which assets are maintained with the Eligible Securities Depository, § 270.17f–5 will govern the Fund’s (or its custodian’s) use of each Eligible Foreign Custodian, while § 270.17f–7 will govern an Eligible Foreign Custodian’s use of the Eligible Securities Depository.

By the Commission.

Margaret H. McFarland,
Deputy Secretary.

[FR Doc. 00–11000 Filed 5–2–00; 8:45 am]
BILLING CODE 8010–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Parts 203 and 205
(Docket Nos. 92N–0297 and 88N–0258)
RIN 0905–AC81

Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures; Delay of Effective Date; Reopening of Administrative Record

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; delay of effective date; reopening of administrative record.

SUMMARY: The Food and Drug Administration (FDA) is delaying until October 1, 2001, the effective date and reopening the administrative record to receive additional comments regarding certain requirements of a final rule published in the Federal Register of December 3, 1999 (64 FR 67720). The other provisions of the final rule become effective on December 4, 2000. The final rule implements the Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription Drug Amendments of 1992 (PDA) and the FDA Modernization Act of 1997 (the Modernization Act). FDA is delaying the effective date for certain requirements relating to wholesale distribution of prescription drugs by distributors that are not authorized distributors of record. FDA is also delaying the effective date of another requirement that would prohibit blood centers functioning as “health care entities” to act as wholesale distributors of blood derivatives. The agency is taking this action to address numerous concerns about the provisions raised by affected parties.

DATES: The effective date for §§ 203.3(u) and 203.50, and the applicability of § 203(q) to wholesale distribution of blood derivatives by health care entities, added at 64 FR 67720, December 3, 1999, is delayed until October 1, 2001. The administrative record is reopened until July 3, 2000, to receive additional comments on these provisions.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Lee D. Korb, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

PDMA (Public Law 100–293) was enacted on April 22, 1988, and was modified by the PDA (Public Law 102–353, 106 Stat. 941) on August 26, 1992. The PDMA as modified by the PDA amended sections 301, 303, 305, and 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331, 333, 353, 381) to, among other things, establish requirements for the wholesale distribution of prescription drugs.

Section 503(e)(1)(A) of the act states that each person who is engaged in the wholesale distribution of a prescription drug who is not the manufacturer or an authorized distributor of record for the drug must, before each wholesale distribution of a drug, provide to the person receiving the drug a statement (in such form and containing such information as the Secretary may require) identifying each prior sale, purchase, or trade of the drug, including the date of the transaction and the names and addresses of all parties to the transaction. Section 503(e)(4)(A) of the act states that, for the purposes of section 503(e), the term “authorized distributors of record” means those distributors with whom a manufacturer has established an “ongoing relationship” to distribute the manufacturer’s products.

On December 3, 1999, the agency published final regulations in part 203 (21 CFR part 203) implementing these and other provisions of PDMA (64 FR 67720). Section 203.50 requires that, before the completion of any wholesale distribution by a wholesale distributor of a prescription drug for which the seller is not an authorized distributor of record to another wholesale distributor or retail pharmacy, the seller must provide to the purchaser a statement identifying each prior sale, purchase, or trade of the drug. The identifying statement must include the proprietary and established name of the drug, its dosage, the container size, the number of containers, lot or control numbers of the drug being distributed, the business