public inspection and copying in the Commission's Public Reference Room, 450 Fifth Street, N.W., Washington, D.C. 20549. Electronically submitted comment letters will be posted on the Commission's Internet web site (http: // www.sec.gov).

**FOR FURTHER INFORMATION CONTACT:** *Release No. 34–39454 (OTC Derivatives Dealers) General:* Catherine McGuire, Chief Counsel, Glenn J. Jessee, Special Counsel, or Patrice Gliniecki, Special Counsel, at (202) 942–0073, Division of Market Regulation, Securities and Exchange Commission, 450 Fifth Street, N.W., Mail Stop 7–11, Washington, D.C. 20549.

*Financial Responsibility and Books and Records:* Michael Macchiaroli, Associate Director, at (202) 942–0132, Peter R. Geraghty, Assistant Director, at (202) 942–0177, Thomas K. McGowan, Special Counsel, at (202) 942–4886, Christopher Salter, Attorney, at (202) 942–0148, Matt Hughey, Accountant, at (202) 942–0143, or Gary Gregson, Statistician, at (202) 942–4156, Division of Market Regulation, Securities and Exchange Commission, 450 Fifth Street, N.W., Mail Stop 2–2, Washington, D.C. 20549.

*Release Nos. 34–39455 (Net Capital Rule—Interest Rate Instruments) and 34–39456 (Net Capital Rule—Concept Release):* Michael Macchiaroli, Associate Director, at (202) 942–0132, Peter R. Geraghty, Assistant Director, at (202) 942–0177, Thomas K. McGowan, Special Counsel, at (202) 942–4886, Christopher Salter, Attorney, at (202) 942–0148, or Gary Gregson, Statistician, at (202) 942–4156, Division of Market Regulation, Securities and Exchange Commission, 450 Fifth Street, N.W., Mail Stop 2–2, Washington, D.C. 20549.

**SUPPLEMENTARY INFORMATION:** On December 17, 1997, the Commission issued for comment Release No. 34–39454, soliciting comment on proposed rules and rule amendments under the Exchange Act that would tailor capital, margin, and other broker-dealer regulatory requirements to a class of registered dealers, called OTC derivatives dealers, active in over-the-counter derivatives markets. The proposed regulations for OTC derivatives dealers are intended to allow securities firms to establish dealer affiliates that would be able to compete more effectively against banks and foreign dealers in global over-the-counter markets. The Commission originally requested that comments on the proposed rules and rule amendments be received by March 2, 1998.

On December 17, 1997, the Commission also issued for comment two releases relating to the Commission's capital requirements for broker-dealers. In Release No. 34–39455, the Commission solicited comment on proposed amendments to Rule 15c3–1 [17 CFR 240.15c3–1] under the Exchange Act that would alter the charges, or ''haircuts,'' from net worth in computing net capital for certain interest rate instruments, including government securities, investment grade nonconvertible debt securities, certain mortgage-backed securities, money market instruments, and debt-related derivative instruments. In Release No. 34–39456, the Commission solicited comment on a concept release considering the extent to which statistical models should be used in setting the capital requirements for a broker-dealer's proprietary positions. The Commission originally requested that comments on these two releases be received by March 30, 1998.

The Commission has recently received requests from interested persons to extend the comment periods for these three releases. The Commission believes that extending the comment periods is appropriate in order to give the public additional time to comment on the matters the releases address. Therefore, the comment period for Release No. 34–39454 (OTC Derivatives Dealers) is extended from March 2, 1998 to April 6, 1998, and the comment periods for Release Nos. 34–39455 (Net Capital Rule—Interest Rate Instruments) and 34–39456 (Net Capital Rule—Concept Release) are extended from March 30, 1998 to May 4, 1998.

By the Commission.

Dated: February 27, 1998.

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 98–5775 Filed 3–5–98; 8:45 am]

**BILLING CODE 8010–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

## 21 CFR Part 314

**[Docket No. 97P–0044]**

## New Drugs for Human Use; Clarification of Requirements for Patent Holder Notification

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend its regulations on notice of certification of invalidity or noninfringement of a patent to provide additional methods for new drug and abbreviated new drug applicants to provide notice to patent owners and new drug application (NDA) holders, without removing the existing means. These proposed amendments reflect current business practices and are intended to ensure that notice is provided to patent owners and NDA holders in a timely manner. FDA is also proposing to require certain applicants to submit to FDA a copy of the notice of certification.

**DATES:** Submit written comments by June 4, 1998.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Leanne Cusumano, 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

Under §§ 314.52(a) and 314.95(a) (21 CFR 314.52(a) and 314.95(a)), new drug and abbreviated new drug applicants provide notice of certification of invalidity or noninfringement of a patent to patent owners and NDA holders by registered or certified mail, return receipt requested, or by another method approved in advance by the agency. Sections 314.52(c) and 314.95(c) set forth the content requirements of the notice of certification. Under § 314.52(e) and § 314.95(e), applicants must amend their applications to document receipt of the notice of certification by each person provided the notice. Applicants must include a copy of the return receipt or other similar evidence of the date the notification was received. FDA accepts as adequate documentation of the date of receipt a return receipt or a letter acknowledging receipt by the person provided the notice. Under § 314.52(e) and § 314.95(e), applicants may rely on another form of documentation only if FDA has agreed to such documentation in advance.

FDA is proposing to amend these regulations to provide additional methods of giving notice of certification without removing the existing means. On February 4, 1997, FDA received a citizen petition from McKenna & Cuneo, L.L.P., on behalf of the National

Pharmaceutical Alliance (Docket No. 97P–0044/CP1). The petitioner requested that FDA revise §§ 314.52(a) and 314.95(a) to permit notice to patent owners and NDA holders to be given by means in addition to ''registered or certified mail, return-receipt requested.'' The petition also requested that FDA clarify the meaning of the phrase ''by mail or in person'' as used throughout FDA's regulations. The petitioner stated that most FDA regulations require submissions to be made by mail or personal delivery, whereas the patent notification provisions require that notice be provided by registered or certified mail, return receipt requested. The petitioner argued that ''return receipt service can result in inefficient and variable document delivery in certain time-sensitive instances,'' (petition at 2), and that ''a change in the patent certification regulations to include delivery via messenger, delivery and mailing services that provide delivery verification would enable the pharmaceutical industry to utilize efficient, standard business practices for document delivery'' (petition at 4–5).

## II. Description of the Proposed Rule

After careful research, FDA decided to propose this regulation in response to the citizen petition. FDA concluded that technological and market changes warrant adoption of regulations permitting notification to patent owners and NDA holders to be given by means in addition to registered or certified mail, return receipt requested. Since §§ 314.52(a) and 314.95(a) were proposed in 1989 (54 FR 28872, July 10, 1989) and finalized in 1994 (59 FR 50338 at 50366, October 3, 1994), the use of private and alternative delivery services has increased dramatically. Between 1988 and 1994, the U.S. Postal Service's market share of mail delivery services dropped from 77 percent to 62 percent, or 15 percentage points (Ref. 1). This means that mail is delivered by means other than the U.S. Postal Service 38 percent of the time. *Nation's Business* (Ref. 2) reports that in 1997:

> [t]he Postal Service now handles about 60 percent of the nation's business-to-business mail, and some in the industry say the figure might drop to 40 percent within five years. Even with its recent upsurge in advertising mail and Priority Mail, the Postal Service's total mail volume increased only 1 percent last year.

In addition, mail services in general are losing market share to facsimiles and e-mail (Refs. 2, 3, and 4).

Under the current regulation, FDA permits notification by means other than registered or certified mail, return receipt requested, but applicants must obtain FDA approval in advance of using an alternative form of documentation (§§ 314.52(e) and 314.95(e)). FDA is interested in ensuring that patent owners and NDA holders receive notification of actions that may affect their patents. Accordingly, all delivery methods that provide verification of receipt serve FDA's purpose. An acceptable verification of receipt includes a receipt that contains the same general type of information as that provided by registered or certified mail, return receipt requested: (1) The address where the article is delivered, (2) identification of the item delivered, (3) the date of receipt, (4) the method of delivery, and (5) the signature of the addressee or his or her agent. To permit applicants to use delivery methods other than registered or certified mail, return receipt requested, FDA is proposing to revise §§ 314.52(a) and 314.95(a) to permit patent certifications to be delivered ''by mail or personal delivery'' for which the applicant obtains ''verification of receipt.''

To explain the phrase ''by mail or personal delivery'' in §§ 314.52(a) and 314.95(a), FDA is proposing to amend § 314.3(b) (21 CFR 314.3(b)) to include the following definition: ''*By mail or personal delivery* means delivery by registered or certified mail, return receipt requested or by an express mail, messenger, delivery, or mailing service, including electronic mailing service or facsimile, provided that verification of receipt is obtained.''

To assist recipients in identifying patent notifications received by means other than by registered or certified mail, return receipt requested, FDA is proposing to amend §§ 314.52(c)(8) and 314.95(c)(8), ''Content of a notice,' to add specific instructions regarding the envelope, and type size and leading of the caption label with the words ''PATENT CERTIFICATION.'' E-mail notices shall state ''PATENT CERTIFICATION'' as the subject line and as the first line of text of the e-mail message.

To clarify the meaning of the phrase ''verification of receipt'' in §§ 314.52(a) and 314.95(a), FDA is proposing to amend §§ 314.52(e) and 314.95(e), ''Documentation of receipt of notice,'' to state that verification of receipt must contain the date notice was delivered, the address to which notice was delivered, and the signature of the recipient.

To accommodate delivery by electronic means, FDA is proposing to amend §§ 314.52(e) and 314.95(e) to permit delivery by electronic mail or facsimile provided certain additional requirements are met. Electronic signatures and electronic records, which includes e-mail and electronic facsimiles, would be required to comply with the provisions of 21 CFR part 11. Facsimile receipts would include the telephone number to which notice was faxed, but would not be required to include the recipient's signature. Electronic mail receipts would include the e-mail address to which notice was delivered, but would not be required to include the recipient's signature.

FDA is also proposing to amend § 314.52(e) to require under section 505(b) of the act (21 U.S.C. 355(b)) applicants to submit a copy of the notice to the agency with the delivery receipt. FDA is proposing this requirement in order to obtain additional information about the relationship between the section 505(b) of the act application and the reference drug(s). This information is particularly desirable in order to avoid confusion in cases in which the section 505(b) of the act application refers to multiple reference drugs.

FDA reminds those providing notice of certification to application holders that if an application holder does not reside or maintain a place of business within the United States, notice must be sent to the application holder's U.S. attorney, agent, or other authorized official (§§ 314.52(a)(2) and 314.95(a)(2)).

FDA seeks comments on this proposal. In particular, FDA is seeking comments addressing the type of receipt which is sufficient to verify deliveries made by electronic mail and facsimile. FDA is also seeking comments regarding how applicants may obtain the correct electronic or facsimile addresses for patent owners and NDA holders in order to ensure that notification is received by a responsible person.

## III. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Data Analysis Group, ''Market Share of Mail Delivery Services,'' *Computer Industry Forecasts*, April 15, 1996.

2. Bates, S., ''Postal Service Tackles Competition,'' *Nation's Business*, April 1997, 38.

3. Blum, A., ''Two-Day Express Market Taking Off,'' *Journal of Commerce*, June 9, 1997, News section, 1A.

4. Goldstein, M. A., ''Can the U.S. Postal Service Market Itself to Success?'' *Los Angeles Times Magazine*, December 11, 1996, 14.

## IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a class

of actions that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

**V. Analysis of Impacts**

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354 and Pub. L. 104–121). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order and so is not subject to further review under the Executive Order. The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this regulation imposes only alternative reporting, recordkeeping, or other economic burdens, the agency certifies that the proposed rule will not have a significant impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

**VI. Paperwork Reduction Act of 1995**

The proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown below.

*Title*: New Drugs for Human Use; Clarification of Requirements for Patent Holder Notification

*Description*: The Food and Drug Administration (FDA) is proposing to amend its regulations on notice of certification of invalidity or noninfringement of a patent to provide additional methods for new drug and abbreviated new drug applicants to provide notice to patent owners and NDA holders, without removing the existing means. These proposed amendments reflect current business practices and are intended to ensure that notice is provided to patent owners and NDA holders in a timely manner. FDA is also proposing to require applicants to submit to FDA a copy of the notice of certification.

*Respondent Description*: Businesses and other for-profit organizations, State or local governments, Federal agencies, and nonprofit institutions.

FDA has determined that the information collection provisions of this proposed rule would not impose any additional burdens that have not already been estimated and submitted to OMB for approval under OMB No. 0910–0305 ''Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions.'' There are additional burdens in this proposed rule that are not already required under current regulations (and specifically approved under OMB No. 0910–0305): (1) New §§ 314.52(c)(8) and 314.95(c)(8) would require the heading ''Patent Certification'' as well as certain print specifications on certain notices. (2) A proposed amendment to § 314.52(e) would require section 505(b) of the act applicants to submit a copy of the notice of certification as an attachment to the verification of receipt. FDA believes that the time and cost for respondents to comply with these new requirements are negligible. The required heading and print specifications would not add any measurable costs to the current requirement for preparing and delivering a notice of certification. Respondents are already required to submit to FDA a certification of receipt, and attaching a copy of the notice of certification would not result in any measurable burden.

**List of Subjects in 21 CFR Part 314**

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 314 be amended as follows:

## PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG

1. The authority citation for 21 CFR part 314 continues to read as follows:

**Authority**: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371, 374, 379e.

2. Section 314.3 is amended in paragraph (b) by alphabetically adding a definition for ''By mail or personal delivery,'' to read as follows:

**§ 314.3 Definitions.**

* * * * *

(b) * * *

* * * * *

*By mail or personal delivery* means delivery by registered or certified mail, return receipt requested or by an express mail, messenger, delivery, or mailing service, including electronic mailing service or facsimile, provided that verification of receipt is obtained.

* * * * *

3. Section 314.52 is amended by revising the introductory text of paragraph (a) and paragraph (e) and adding paragraph (c)(8) to read as follows:

**§ 314.52 Notice of certification of invalidity or noninfringement of a patent.**

(a) *Notice of certification*. For each patent that claims the drug or drugs on which investigations that are relied upon by the applicant for approval of its application were conducted or that claims a use for such drug or drugs and that the applicant certifies under § 314.50(i)(1)(i)(A)(*4*) that a patent is invalid, unenforceable, or will not be infringed, the applicant shall give notice of such certification by mail or personal delivery to and shall obtain verification of receipt from each of the following persons: * * *

* * * * *

(c) * * *

(8) The envelope, where applicable, and cover sheet of the notice shall be clearly labeled in 14 point or larger, bold, all capitals type with the words ''PATENT CERTIFICATION.'' E-mail notices shall state ''PATENT CERTIFICATION'' as the subject line and as the first line of text of the e-mail message.

* * * * *

(e) *Documentation of receipt of notice*. The applicant shall amend its application to document receipt of the notice required under paragraph (a) of this section by each person provided the notice. The applicant shall include a copy of the return receipt or other similar evidence of the date the notification was received. A copy of the notice shall be attached to the receipt submitted to the agency if the applicant has made a submission under 21 U.S.C. 355(b). FDA will accept as adequate documentation of the date of receipt a return receipt from registered or certified mail, a letter acknowledging receipt by the person provided the notice, or a verification of receipt that contains the date notice was delivered, the address to which notice was delivered, and the signature of the recipient. Electronic signatures and electronic records shall comply with the provisions of 21 CFR part 11. Facsimile receipts shall also include the telephone number to which notice was faxed, but

need not include the recipient's signature. Electronic mail receipts shall also include the e-mail address to which notice was delivered, but need not include the recipient's signature. An applicant may rely on another form of documentation only if FDA has agreed to such documentation in advance.

* * * * *

4. Section 314.95 is amended by revising the introductory text of paragraph (a) and paragraph (e) and adding paragraph (c)(8) to read as follows:

**§ 314.95 Notice of certification of invalidity or noninfringement of a patent.**

(a) *Notice of certification*. For each patent that claims the listed drug or that claims a use for such listed drug for which the applicant is seeking approval and that the applicant certifies under § 314.94(a)(12) is invalid, unenforceable, or will not be infringed, the applicant shall give notice of such certification by mail or personal delivery to and shall obtain verification of receipt from each of the following persons:* * *

* * * * *

(c) * * *

(8) The envelope, where applicable, and cover sheet of the notice shall be clearly labeled in 14 point or larger, bold, all capitals type with the words ''PATENT CERTIFICATION.'' E-mail notices shall state ''PATENT CERTIFICATION'' as the subject line and as the first line of text of the e-mail message.

* * * * *

(e) *Documentation of receipt of notice*. The applicant shall amend its abbreviated application to document receipt of the notice required under paragraph (a) of this section by each person provided the notice. The applicant shall include a copy of the return receipt or other similar evidence of the date the notification was received. FDA will accept as adequate documentation of the date of receipt a return receipt from registered or certified mail, a letter acknowledging receipt by the person provided the notice, or a verification of receipt that contains the date notice was delivered, the address to which notice was delivered, and the signature of the recipient. Electronic signatures and electronic records shall comply with the provisions of 21 CFR part 11. Facsimile receipts shall also include the telephone number to which notice was faxed, but need not include the recipient's signature. Electronic mail receipts shall also include the e-mail address to which notice was delivered, but need not include the recipient's signature. An applicant may rely on another form of documentation only if FDA has agreed to such documentation in advance.

* * * * *

Dated: February 26, 1998.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

[FR Doc. 98–5800 Filed 3–5–98; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF THE TREASURY

## Internal Revenue Service

## 26 CFR Part 1

**[REG–208299–90]**

**RIN 1545–AP01**

## Allocation and Sourcing of Income and Deductions Among Taxpayers Engaged in a Global Dealing Operation

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of proposed rulemaking and notice of public hearing.

**SUMMARY:** This document contains proposed rules for the allocation among controlled taxpayers and sourcing of income, deductions, gains and losses from a global dealing operation; rules applying these allocation and sourcing rules to foreign currency transactions and to foreign corporations engaged in a U.S. trade or business; and rules concerning the mark-to-market treatment resulting from hedging activities of a global dealing operation. These proposed rules affect foreign and domestic persons that are participants in such operations either directly or indirectly through subsidiaries or partnerships. These proposed rules are necessary to enable participants in a global dealing operation to determine their arm's length contribution to a global dealing operation. This document also provides notice of a public hearing on these proposed regulations.

**DATES:** Written comments must be received by June 4, 1998. Outlines of oral comments to be discussed at the public hearing scheduled for July 9, 1998, must be received by June 18, 1998.

**ADDRESSES:** Send submissions to: CC:DOM:CORP:R (REG–208299–90), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered between the hours of 8 a.m. and 5 p.m. to: CC:DOM:CORP:R (REG–208299–90), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, N.W., Washington, D.C. Alternatively, taxpayers may submit comments electronically via the Internet by selecting the ''Tax Regs'' option on the IRS Home Page, or by submitting comments directly to the IRS Internet site at http://www.irs.ustreas.gov/prod/tax_regs/comments.html. The public hearing will be held in room 2615, Internal Revenue Building, 1111 Constitution Avenue, NW, Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Concerning the regulations in general, Ginny Chung of the Office of Associate Chief Counsel (International), (202) 622–3870; concerning the mark-to-market treatment of global dealing operations, Richard Hoge or JoLynn Ricks of the Office of Assistant Chief Counsel (Financial Institutions & Products), (202) 622–3920; concerning submissions and the hearing, Michael Slaughter, (202) 622–7190 (not toll-free numbers).

**SUPPLEMENTARY INFORMATION:**

### Paperwork Reduction Act

The collections of information contained in this notice of proposed rulemaking have been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collections of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance officer, T:FS:FP, Washington, DC 20224. Comments on the collections of information should be received by May 5, 1998.

Comments are specifically requested concerning: Whether the proposed collections of information are necessary for the proper performance of the functions of the Internal Revenue Service, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collections of information (see below);

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collections of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.