DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

15 CFR Part 806

[Docket No. 060131020–6152–02]

RIN 0691–AA57

Direct Investment Surveys: BE–577, Direct Transactions of U.S. Reporter With Foreign Affiliate

AGENCY: Bureau of Economic Analysis, Commerce.

ACTION: Final rule.

SUMMARY: This final rule amends regulations of the Department of Commerce, Bureau of Economic Analysis (BEA), for the quarterly BE–577, Direct Transactions of U.S. Reporter With Foreign Affiliate.

The BE–577 survey is conducted quarterly and is a sample survey that obtains data on transactions and positions between U.S.-owned foreign business enterprises and their U.S. parents. To address the current needs of data users while at the same time keeping the respondent burden as low as possible, BEA is modifying, adding, or deleting items on the survey form and in the reporting criteria. The changes will bring the BE–577 form and related instructions into conformity with the 2004 BE–10, Benchmark Survey of U.S. Direct Investment Abroad and will exclude data that have recently begun to be collected on other Government surveys.

DATES: This final rule will be effective July 20, 2006.

FOR FURTHER INFORMATION CONTACT: Obie G. Whichard, Chief, International Investment Division (BE–50), Bureau of Economic Analysis, U.S. Department of Commerce, Washington, DC 20230; phone (202) 606–9890 or e-mail (*obie.whichard@bea.gov*).

SUPPLEMENTARY INFORMATION: In the March 1, 2006, **Federal Register**, 71 FR 10454, BEA published a notice of proposed rulemaking setting forth revised reporting requirements for the BE–577, Direct Transactions of U.S. Reporter With Foreign Affiliate. No comments on the proposed rule were received. Thus, the proposed rule is adopted without change. This final rule amends 15 CFR 806.14 to set forth the reporting requirements for the BE–577, Direct Transactions of U.S. Reporter With Foreign Affiliate.

Description of Changes

The BE–577, Direct Transactions Of U.S. Reporter With Foreign Affiliate, is a mandatory survey and is conducted quarterly by BEA under the International Investment and Trade in Services Survey Act (22 U.S.C. 3101–3108). BEA will send BE–577 survey forms to potential respondents each quarter; responses will be due within 30 days after the close of each fiscal quarter, except for the final quarter of the fiscal year, when reports will be due within 45 days.

The final rule increases the exemption level for reporting on the BE–577 from $30 million to $40 million. The exemption level is stated in terms of the foreign affiliate's assets, sales, and net income.

In addition to the change in the reporting criteria mentioned above, BEA is introducing a few changes to the survey form and instructions. BEA is: (1) Revising the survey form and instructions to bring them into conformity with the most recent BE–10 benchmark survey instructions for reporting capital gains and losses; (2) collecting information on payments to and receipts from foreign affiliates for interest, royalties and license fees and other private services gross of any taxes withheld to align reporting of these items with current international statistical standards for balance of payments accounts (previously, this information was collected net of taxes withheld); (3) modifying the survey instructions to indicate that positions and transactions in financial derivatives contracts that are reported on or derived from the Treasury Department's recently instituted International Capital Form D, Report of Holdings of, and Transactions in, Financial Derivatives Contracts with Foreign Residents should be excluded from BE–577 reports; and (4) removing the requirement for reporting certain affiliated insurance transactions that have been problematic to collect on the BE–577. BEA plans to move the reporting requirement for these transactions to specialized services surveys that BEA conducts in the near future.

Survey Background

BEA will conduct the survey under the International Investment and Trade in Services Survey Act (22 U.S.C. 3101–3108), hereinafter, ''the Act.'' Title 22 United States Code, Section 3103(a)(1) of the Act requires that with respect to United States direct investment abroad, the President shall conduct a data collection program to obtain current information on international capital flows and other information related to international investment and trade in services including information that may be necessary for computing and analyzing the United States balance of payments, the employment and taxes of United States parents and affiliates, and the international investment and trade in services position of the United States.

In Section 3 of Executive Order 11961, the President delegated authority granted under the Act as concerns direct investment to the Secretary of Commerce, who has redelegated it to BEA. The quarterly survey of U.S. direct investment abroad is a sample survey that covers all foreign affiliates above a size-exemption level. The survey collects data on transactions and positions between U.S.-owned foreign business enterprises and their U.S. parents. The sample data are used to derive quarterly universe estimates from similar data reported in the BE–10, Benchmark Survey of U.S. Direct Investment Abroad, which is taken every five years. The data are used in the preparation of the U.S. international transactions accounts, input-output accounts, and national income and product accounts. The data are needed to measure the size and economic significance of U.S. direct investment abroad, measure changes in such investment, and assess its impact on the U.S. and foreign economies. The data are disaggregated by country and industry of foreign affiliate.

Executive Order 12866

This final rule has been determined to be not significant for purposes of E. O. 12866.

Executive Order 13132

This final rule does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under E.O. 13132.

Paperwork Reduction Act

The collection-of-information in this final rule has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA).

Notwithstanding any other provisions of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection-of-information subject to the requirements of the Paperwork Reduction Act unless that collection displays a currently valid OMB control number. The OMB control number for the BE–577 is 0608–0004; the collection will display the number.

The survey is expected to result in the filing of about 13,500 foreign affiliate reports by an estimated 1,500 U.S. parent companies. The respondent burden for this collection of information

is estimated to vary from 0.5 hour to 4 hours per response, with an average of 1.25 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Because reports are filed 4 times per year, 54,000 responses annually are expected. Thus, the total annual respondent burden of the survey is estimated at 67,500 hours (13,500 respondents times 4 times 1.25 hours average burden). This estimate is the same as the burden hours currently carried for this collection in the OMB inventory.

Comments regarding the burden estimate or any other aspect of this collection of information should be addressed to: Director, Bureau of Economic Analysis (BE–1), U.S. Department of Commerce, Washington, DC 20230, fax: 202–606–5311; and the Office of Management and Budget, O.I.R.A., Paperwork Reduction Project 0608–0004, Attention PRA Desk Officer for BEA, via the Internet at *pbugg@omb.eop.gov*, or by fax at 202–395–7245.

Regulatory Flexibility Act

The Chief Counsel for Regulation, Department of Commerce, has certified to the Chief Counsel for Advocacy, Small Business Administration, under the provisions of the Regulatory Flexibility Act (5 U.S.C. 605(b)), that this rule will not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. No comments were received regarding the economic impact of the rule. As a result, no final regulatory flexibility analysis was prepared.

List of Subjects in 15 CFR Part 806

International transactions, Economic statistics, U.S. investment abroad, Penalties, Reporting and recordkeeping requirements.

Dated: May 26, 2006.

J. Steven Landefeld,

Director, Bureau of Economic Analysis.

■ For the reasons set forth in the preamble, BEA is amending 15 CFR part 806 as follows:

PART 806—DIRECT INVESTMENT SURVEYS

■ 1. The authority citation for 15 CFR part 806 continues to read as follows:

Authority: 5 U.S.C. 301; 22 U.S.C. 3101–3108; E.O. 11961 (3 CFR, 1977 Comp., p. 86), as amended by E.O. 12318 (3 CFR, 1981 Comp., p. 173); E.O. 12518 (3 CFR, 1985 Comp., p. 348).

§ 806.14 [Amended]

■ 2. Section 806.14 (e) is amended by removing ''$30,000,000'' and adding ''$40,000,000'' in its place.

[FR Doc. E6–9608 Filed 6–19–06; 8:45 am]

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[Docket No. DoD–2006–HA–0143]

RIN 0720–0057

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/ TRICARE; Coverage of Phase II and Phase III Clinical Trials Sponsored by the National Institutes of Health National Cancer Institute

AGENCY: Office of the Secretary, DoD.

ACTION: Final rule.

SUMMARY: The final rule allows the Department of Defense to waive normal requirements so that covered beneficiaries can participate in Phase II and Phase III clinical trials sponsored or approved by the National Institutes of Health National Cancer Institute (NIH NCI). This waiver authority is expected to promote beneficiary access to promising new treatments and contribute to the development of such treatments.

DATES: This rule is effective July 20, 2006.

ADDRESSES: TRICARE Management Activity (TMA), Medical Benefits and Reimbursement System, 16301 East Centretech Parkway, Aurora, CO 80011–9066

FOR FURTHER INFORMATION CONTACT: Debra Hatzel, Medical Benefits and Reimbursement Systems, TMA, telephone (303) 676-3572. Questions regarding payment of specific claims under TRICARE should be addressed to the appropriate TRICARE contractor.

SUPPLEMENTARY INFORMATION:

I. Background

This final rule implements Title 10, United States Code, section 1079(a)(13) which provides for a waiver of the general prohibition on coverage of unproven medical treatments or procedures in connection with clinical trials sponsored or approved by the National Institutes of Health National Cancer Institute. This waiver is contingent upon the Secretary of Defense's determination that a waiver will promote access to promising new treatments and contribute to the development of such treatments. Based on the improved beneficiary access to these trials, and the contributions to the development of such treatments, it is in the best interest of the Department and its beneficiaries to continue to provide access through an authorized waiver as outlined in the proposed rule.

Clinical trials are the major avenue for discovering, developing, and evaluating new cancer therapies, and clinical trial participants are among the first to receive new cancer prevention or treatment methods before they are widely available. Many significant medical discoveries in this field have occurred as a direct result of clinical trial participation. For example, because of survival improvements seen in an NCI-sponsored clinical trial, early initiation of hormonal therapy has become the standard of care in node-positive prostrate cancer patients. Even when they do not lead to new therapies, clinical trials often answer important questions and help move research forward so that others may prevent or survive this disease.

Cancer treatment trials may include testing new drugs, new approaches to surgery or radiation therapy, new combinations of treatments, or new methods such as gene therapy. Studies that involve drugs or invasive procedures are categorized by phase. Phase I trials evaluate new cancer drugs to determine what dose is safe, how a new agent should be administered (by mouth, injected into a vein, or injected into the muscle), and how frequently the treatment should be given. After safety parameters have been established, Phase II trials are conducted to assess the effectiveness of an agent or intervention against a specific type of cancer. Phase III trials compare effective treatments from Phase II studies to conventional cancer treatments. Clinical trials offer high quality care for cancer prevention and treatment, and no patient ever receives a placebo (substance with active ingredients) when effective care exists.

The Department of Defense (DoD) and the National Cancer Institute (NCI) established a partnership in 1994 to conduct a demonstration project that allowed patients with breast cancer to participate in NCI-sponsored bone marrow transplant clinical trials. This demonstration project expanded in 1996 to include all cancers and NCI-sponsored Phase II and III cancer treatment clinical trials. The DoD–NCI demonstration partnership was further