

(manufacturers and distributors); Schedule III narcotic materials (manufacturers and distributors); and selected Schedules III and IV psychotropic controlled substances (manufacturers only). This proposal would add Schedule III GHB drug products to this list.

In addition, Public Law 106–172, Section 4 (amending 21 U.S.C. 827(h)(6)) recommended that DEA apply the mail order reporting requirements of 21 U.S.C. 830(b)(3) to “gamma hydroxybutyric acid to the same extent and in the same manner as such section applies with respect to the chemicals and drug products specified in subparagraph (A)(i) of such section.” While DEA is proposing the amendment of its regulations to include these provisions, Congress also passed Pub. L. 106–310, the “Children’s Health Act of 2000”, Title XXXVI of which is the Methamphetamine Anti-Proliferation Act of 2000 (MAPA). One of the consequences of MAPA was to redesignate 21 U.S.C. 830(b)(3)(A)(i) as 21 U.S.C. 830(b)(3)(B)(i). Further, MAPA required mail order reporting requirements for export transactions involving ephedrine, pseudoephedrine, or phenylpropanolamine. These reporting requirements would not apply to distributions of drug products, including GHB, pursuant to a valid prescription, which were excluded under MAPA (21 U.S.C. 830(b)(3)(D)). Regulations implementing the Methamphetamine Anti-Proliferation Act of 2000 were published October 7, 2003 (68 FR 57799). Thus, the net effect is that all export transactions involving GHB be reported to DEA. Transactions involving prescriptions of GHB are not required to be reported to DEA.

### Regulatory Certifications

#### *Regulatory Flexibility Act*

The Deputy Assistant Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation, and by approving it certifies that it will not have a significant economic impact upon a substantial number of small entities. This rulemaking creates new recordkeeping and reporting requirements which will have an extremely limited impact on a small number of registrants due to the restricted use of GHB for legitimate medical purposes. As a condition of Xyrem’s® (the FDA-approved product containing GHB) approval, a risk management program was designed to limit its distribution. Under this program, Xyrem® will only be available

to physicians and patients through a single centralized pharmacy. As a result of this program, at this time, controlled substances distributors and retail pharmacies will not be handling Xyrem® and, thus, will not be affected by these requirements. For those few persons affected by these proposed regulations, the information requested by these added records is readily and commonly available, and due to the limited distribution of GHB the impact on reporting requirements should be minimal.

#### *Executive Order 12866*

The Deputy Assistant Administrator further certifies that this regulation has been drafted in accordance with the principles of Executive Order 12866, Section 1(b). This action has been determined to be a “significant regulatory action” under Executive Order 12866, and accordingly this proposed rule has been reviewed by the Office of Management and Budget.

#### *Executive Order 12988*

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988.

#### *Executive Order 13132*

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

#### *Unfunded Mandates Reform Act of 1995*

This rulemaking will not result in the expenditure by state, local, and tribal governments in the aggregate, or by the private sector, of \$100 million or more in any one year, and would not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

#### *Paperwork Reduction Act*

While, technically, this rule requires new, minimal recordkeeping and reporting requirements for drug products containing GHB, DEA does not believe that these recordkeeping and reporting requirements create any greater hour or cost burden for respondents than what already exists. Records required to be maintained by practitioners under proposed 21 CFR 1304.26, including the practitioner’s name, address, state license and federal registration numbers, and the patient’s

insurance provider (if available) are all records which are maintained as a usual course of professional practice by a practitioner. The reporting requirements proposed under 21 CFR 1304.33 are part of an already-approved collection of information (OMB 1117–0003: ARCOS Transaction Reporting—DEA Form 333). DEA believes that the additional reporting requirements will have no impact on the hour or cost burden for respondents as reports are generated and submitted electronically. As has been stated previously, due to the risk management plan established for Xyrem® (the FDA-approved product containing GHB) this product has an extremely limited distribution potential. Because of the nature of this product’s distribution, DEA anticipates that fewer than five persons will be impacted by the requirement to report handling Schedule III GHB products to ARCOS, and those persons are already filing reports with DEA for other controlled substances handled. The system modifications necessary to generate this report will occur as a normal part of a registrant’s handling of this product. Therefore, DEA is not submitting any changes or amendments to its active information collections under the Paperwork reduction Act of 1995.

#### *Small Business Regulatory Enforcement Fairness Act of 1996*

This rulemaking is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation or on the ability of U.S.-based companies to compete with foreign-based companies in domestic and export markets.

### List of Subjects

#### *21 CFR Part 1304*

Drug traffic control, Reporting and recordkeeping requirements.

#### *21 CFR Part 1306*

Drug traffic control, Prescription drugs.

#### *21 CFR Part 1310*

Drug traffic control, List I and List II chemicals, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR Parts 1304, 1306 and 1310 are proposed to be amended as follows: