

PART 1304 — RECORDS AND REPORTS OF REGISTRANTS

CONTINUING RECORDS

§1304.26 Additional recordkeeping requirements applicable to drug products containing gamma-hydroxybutyric acid.

In addition to the recordkeeping requirements for dispensers and researchers provided in **Sec. 1304.22**, practitioners dispensing gamma- hydroxybutyric acid that is manufactured or distributed in accordance with an application under section 505 of the Federal Food, Drug, and Cosmetic Act must maintain and make available for inspection and copying by the Attorney General, all of the following information for each prescription:

- (a) Name of the prescribing practitioner.
- (b) Prescribing practitioner's Federal and State registration numbers, with the expiration dates of these registrations.
- (c) Verification that the prescribing practitioner possesses the appropriate registration to prescribe this controlled substance.
- (d) Patient's name and address.
- (e) Patient's insurance provider, if available.

[70 FR 293, Jan. 4, 2005]