(Manufacturer to supply the following details of dosage:

1. Usual starting dose.
2. Maximum dose.
3. Dose beyond which a response is usually not seen if patient has not already had some response.
4. Usual maintenance dose.
5. Dosage interval, with reasons, e.g., avoid GI intolerance, short half-life of drug, etc.
6. Caution regarding dosage in elderly.)

HOW SUPPLIED

(To be supplied by manufacturer.)

(d) Each holder of an approved new drug application for an oral hypoglycemic agent shall submit a supplement to his application under the provisions of § 314.8(d) of this chapter to provide for labeling as described in paragraphs (b) and (c) of this section. The labeling in such supplement shall be identical in wording to the labeling in paragraphs (b) or (c) of this section where precise wording is specified, shall provide information on each of the points where wording is delegated to the manufacturer, and shall contain no additional or extraneous information. Such supplement shall be submitted within 10 days after (effective date of the final regulation). Any oral hypoglycemic drug with labeling not in compliance with this section and shipped into interstate commerce after (60 days after effective date of the final regulation) shall be subject to regulatory action.