SECTION 1.106(b)(3)

The information required by this subsection is designed for communication to, and use by, practitioners licensed by law to administer prescription legend drugs. However, in the usual course of employing such a drug, the prescriber creates a prescription which in turn is communicated to the pharmacist. Therefore, the prescriber does not see either the product or its packaged contents. It is the pharmacist who has physical possession of the product, its container or wrapper, and any written, printed, or graphic material accompanying such an article. Consequently, there is no basis for believing that by increasing the volume of literature included in every prescription drug container, communication of information to prescribers will thereby be facilitated.

A pharmacist with numerous packages of a particular drug in stock will have numerous copies of the same literature, which will seldom or never be seen by the prescriber. Moreover, as supplementary information develops, each existing product container and enclosures would be incomplete, inaccurate, or otherwise deficient under the proposed regulations.

A realistic appraisal of product expense for initial packaging, shipping, and storage in relation to the degree of product information communicated to prescribers which might be achieved by the proposed procedures will reveal the impracticality of this particular mechanism. This significant expense ultimately would have to be passed on to the patient, thereby increasing the cost of his medication, with little hope of achieving the desired purpose of the proposed regulations.

Furthermore, the existence of extensive professional information within each product package increases the risk of this information passing into hands of the laity. Obviously, this might easily result in untoward consequences. It must be remembered that the purpose of exempting drugs, subject to the requirements of Section 503(b)(1) of the Act, from Section 502(f)(1) is to preclude the use of dangerous prescription legend drugs except under the direct supervision of a practitioner licensed by law to administer such drugs.

As an alternative to the proposals contained in this subsection, we recommend a cooperative arrangement, involving the Food and Drug Administration, the pharmaceutical industry, and the health professions immediately involved, through which the following procedures would be effected:

1. Every manufacturer would be charged with the responsibility of preparing, for each product subject to the regulations, a complete "official brochure" containing full professional information.
2. The "official brochure" would be in accordance with the new regulations proposed by the Food and Drug Administration.
3. A non-governmental, non-profit agency approved for that purpose by the Food and Drug Administration, the United States Pharmacopeia Revision Committee, and the Committee on National Formulary would serve as the coordinator and distributor of each "official brochure."
4. The "official brochure" design would be uniform in format and conform to specifications developed by the agency referred to in paragraph 3 with the advice of the United States Pharmacopeia Revision Committee and the Committee on National Formulary.
5. All production, publication, and distribution costs for each "official brochure" would be borne by the respective manufacturer.
6. The agency referred to in paragraph 3 would promptly distribute each "official brochure" to every pharmacy in the United States.
7. Pharmacists would be advised that the availability of these brochures is as essential for the proper information of the medical and pharmacal professions with regard to the drugs involved as is the case with the latest editions of the United States Pharmacopeia and the National Formulary. By state board ruling or by state law the availability of the resulting compilation of "official brochures" could be made a part of the standard prescription equipment of every pharmacy.
8. Additional copies of each "official brochure" would be made available for distribution to pharmacies so that any practitioner licensed to administer the drug described in an "official brochure" could obtain the desired information or a copy of the "official brochure" from a pharmacy as well as from the agency referred to in paragraph 3, or from the manufacturer of the drug.