REVIEW MANAGEMENT

APPLICATIONS FOR PARENTERAL PRODUCTS IN PLASTIC IMMEDIATE CONTAINERS

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PURPOSE This MAPP describes the types of new drug application that will satisfy the requirements in 21 CFR 310.509(a) for a new drug application for approval of any parenteral drug product to be packaged in a plastic immediate container.

BACKGROUND

The Code of Federal Regulations, Title 21, Section 310.509(a) established that any parenteral drug product packaged in a plastic immediate container is a new drug under section 201(p) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and requires an approved new drug application as a condition for marketing. Section 310.509 took effect when 505(b) was the only provision in the FD&C Act for submission of a new drug application. The subsequent enactment of the Drug Price Competition and Patent Term Restoration Act of 1984 (Waxman-Hatch Amendments) replaced 505(b) with 505(b)(1), 505(b)(2) and 505(j), thereby creating three distinct types of applications for approval of new drugs depending on the nature and the source of the evidence required to demonstrate the safety and effectiveness of the new drug product.

REFERENCES

- 21 CFR 310.509 Parenteral Drug Products in Plastic Containers
- 21 CFR 314.3 Definitions

DEFINITIONS

- **Application.** As defined under 21 CFR 314.3, includes all amendments and supplements to the application.

- **Parenteral Drug Product.** A sterile solution intended for administration by injection, internal irrigation, or for use in dialysis procedures.

- **Small Volume Parenteral** (SVP). A parenteral drug product packaged in a volume of less than 100 mL.

- **Large Volume Parenteral** ((LVP). A parenteral product packaged in a volume of 100 mL or more.

- **Limited Confirmatory Testing.** Simple studies intended to rule out unlikely problems. In some cases limited confirmatory testing may include acute animal studies. However, a study to answer basic safety or effectiveness questions or a study that would require substantial scientific review would not be considered limited confirmatory testing.

POLICY

- The requirements for a "new drug application" under 21 CFR 314.509(a) may be satisfied by a new drug application (NDA) submitted in accordance with section 505(b)(1) or section 505(b)(2), an abbreviated new drug application (ANDA) submitted in accordance with section 505(j) or, for antibiotics, an NDA or abbreviated antibiotic application (AADA) submitted in accordance with section 507 of the FD&C Act, or by a supplement to a previously approved application of one of these types.

- An application for approval of a parenteral product in a plastic immediate container may be filed as an ANDA under section 505(j) or, for antibiotics, an AADA under section 507 provided that, 1) the product duplicates an approved product listed in the current edition of *Approved Drug Products with Therapeutic Equivalence Evaluations* ("The Orange Book") and 2) approval of the product in the plastic immediate container does not require studies beyond limited confirmatory testing and the testing described in the USP.

- An application for approval of a parenteral product in a plastic immediate container for which the container requires animal studies beyond limited confirmatory testing and the testing described in the USP to show that the drug

product is safe must be submitted as an NDA under section 505(b) or, for antibiotics, under section 507.

- An application for approval of a parenteral product in a plastic immediate container containing an active ingredient or a combination of active ingredients not previously approved under an application submitted under section 505(b) or section 507, including an application for a product currently marketed in a glass container for which there is no reference listed drug, should be filed as an NDA under section 505(b) or 507 (as appropriate).

    1. Applications filed for approval of new drugs under 505(b) and non-abbreviated applications under 507 are required to contain evidence of safety and effectiveness. Published reports may be adequate for certain applications. However, reference to general recognition of safety and effectiveness is an inadequate basis for approval of a new drug.

    2. Applications filed under 505(b) or 507 for parenteral products in plastic containers that meet the definition of a "human drug application" in the Prescription Drug User Fee Act of 1992 (PDUFA) are subject to user fees.

- This policy applies to both large volume parenteral products and small volume parenteral products.

- This policy applies to applications for parenteral products packaged in plastic immediate containers regardless of whether the plastic material has been previously used to package an approved drug product.

EFFECTIVE DATE

This MAPP is effective upon date of publication.