

## **Plastics in Pharmaceutical Applications**

by

Susan Howe

Vice President, Processors Council

Society of the Plastics Industry (SPI)

Pharmaceutical products (drugs) are those products, intended to perform a chemical or metabolic effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body. Plastics may be used in packaging or delivery of drugs. Plastics, which contact drugs, are regulated by the USA, EU and other countries.

### **USA**

In the United States drugs are regulated under the Federal Food Drug and Cosmetic Act (Section 501 – 505). Standards for medicines, dosage forms, health care products and dietary supplements along with requirements for container closure systems and standards for medical devices are available in the United States Pharmacopoeia ([USP](#)). New drug applications must be submitted to the Food and Drug Administration ([FDA](#)) Center for Drug Evaluation and Research ([CDER](#)). Technical information about the packaging, packaging closure system or delivery device has to be provided as part of the New Drug Application ([NDA](#)). The composition of the packaging, closure system or delivery device materials may be provided directly to the FDA by the material supplier in a Type III Drug Master File (DMF). This allows confidential business information to be available to CDER staff at FDA but not to others in the supply chain. The DMF also contains information about the manufacturing process, biocompatibility and safety of the material. The material supplier must authorize the FDA to review the DMF for drug applications by a specific customer. These authorizations are filed in the DMF and also provided to customers so that they can reference the DMF in applications to FDA.

### **Links to Additional Information**

The FDA regulations for New Drug Applications may be viewed at:

[http://www.access.gpo.gov/nara/cfr/waisidx\\_98/21cfr314\\_98.html](http://www.access.gpo.gov/nara/cfr/waisidx_98/21cfr314_98.html)

SPI Guidance for the Development of Type III Drug Master Files is offered for sale at:

<http://www.plasticsindustry.org/membersonly/about/fdcpmc/fdcpmcpublications.htm>.

FDA Guideline for Submitting Documentation for Packaging for Human Drugs and Biologics

<http://www.fda.gov/cder/guidance/package.htm>

FDA Container Closure Systems for Packaging Human Drugs and Biologics – Chemistry, Manufacturing and Controls Documentation

<http://www.fda.gov/cder/guidance/1714fnl.htm>

Industry information regarding Type III Drug Master Files may also be viewed at

<http://www.dmfworkshop.msu.edu/>

### **Europe**

In Europe Directive [2003/63/EC](#) regulates human medicinal products, and [2004/28/EC](#) regulates veterinary medicinal products including plastics in contact with these products intended for human or veterinary use. The agency responsible for approval of new drugs is the European Medicines Agency ([EMA](#)). EMA has developed a “Guideline on Plastic Immediate Packaging Materials”. This guidance document describes the specific requirements for plastics immediate packaging materials (i.e. plastic material intended to be in direct contact with the active substance or medicinal product), and includes the assessments and documentation required for medicinal products. It replaces the “Guideline on Plastic Primary Packaging Materials (Rules

Governing Medicinal Products) 3AQ10a. The new guideline becomes effective on December 1, 2005. Plastic materials may be listed in the [European Pharmacopoeia](#). If so, the assessment and documentation is simplified. The composition of the plastic materials used must be included as part of the application, as there is no DMF system for the EU. Pharmaceutical products are also approved by EU Member Countries. Some Member States also have pharmacopoeias.

### **Links to Additional Information**

The Guideline on Plastic Immediate Packaging Materials may be downloaded from the following site:

<http://www.emea.eu.int/pdfs/human/qwp/435903en.pdf>

### **Canada**

In Canada, the premarket approval process of all pharmaceutical products includes the regulation of container and closure systems. The Therapeutic Products Directorate (TPD) of Health Canada administers the drug review process. Fees are charged for the registration of new DMFs and for processing of authorizations (letters of access) granted by the DMF owner or authorized agent to specific drug product manufacturers. Material information may be submitted in the form of a Type II DMF. A DMF is a reference source that provides drug evaluators confidential information not available to drug product manufacturers (sponsors) about the specific processes and components used in the manufacturing, processing and packaging of a drug. DMFs are divided into four types:

- Type I: active pharmaceutical ingredients
- Type II: packaging materials
- Type III: colourants, flavours, and other additives
- Type IV: drug products.

### **Links to Additional Information**

[Therapeutic Products Directorate of Health Canada](#)

[Good Manufacturing Practices for Schedule D Drugs, Part 1, Biological Drugs](#) – includes packaging material and final product testing.

[Guidance Documents for Drug and Health Care Products](#) – this site includes links to Good Manufacturing Practices Guidelines, and other useful information.

[Drug Master Files Fees](#)

[Draft Guidance for Industry](#) – Quality (Chemistry and Manufacturing) Guidance: New Drug Submissions (NDs) and Abbreviated New Drug Submissions (ANDs) – this document includes requirements for container closure systems.

Copyright © Society of the Plastics Industry, Inc., November 2005  
Food, Drug, and Cosmetic Packaging Materials Committee  
Medical and Personal Care Products Subcommittee

The Food, Drug, and Cosmetic Packaging Materials Committee (FDCPMC) is a self-funded business unit of The Society of the Plastics Industry, Inc. Since 1957, the FDCPMC has fostered

the use of good science and good public policy in the safe use and regulation of packaging and non-packaging components for food, drugs, personal care products, cosmetics, toys and medical devices. The FDCPMC provides a network for the dissemination of regulatory information and a forum for the discussion of relevant global issues. For more information visit the FDCPMC Web site at <http://www.plasticsindustry.org/about/fdcpmc/index.htm>

For additional information, please contact:

Susan Howe

[showe@plasticsindustry.org](mailto:showe@plasticsindustry.org)

(202) 974-5200