



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Beltsville, MD 20705

COSTER USA, INC.
Attn: Mr. Ray Skowronski
Quality Manager
1625 Shanahan Drive
South Elgin, IL 60177

Dear Sir/Madam:

The Food and Drug Administration acknowledges receipt of the following Drug Master File (DMF) submission:

DMF Number Assigned: 22066 **Date of Submission:** September 26, 2008

DMF Type: III

Title of Submission: Bag-on-Valve (BOV) components and systems as manufactured by Coster USA Inc. and Coster Technologie Speciali S.p.A. in South Elgin, IL and Calceranica al Lago and Caldonazzo, Italy for Coster USA, Inc.

Holder of Submission: Coster USA, Inc.

Submitted by: Coster USA, Inc.

Agent(s): None

All subsequent correspondence to this DMF should be identified with the information as provided above. Submissions to the DMF should be forwarded in duplicate.

Your DMF will be reviewed only in connection with the New Drug Applications, Abbreviated New Drug Applications, Investigational New Drug Applications or any DMFs it is intended to support.

The holder of the DMF is responsible for compliance with the Regulation Title 21 Code of Federal Regulations Part 314.420 as interpreted in "The Guideline for Drug Master Files" [HEW (FDA) 79-3072. www.fda.gov/cder/guidance/dmf.htm]. You are expected to:

- Adhere to the statement of the commitment you have provided
- Provide to the FDA by submission to the DMF in two copies:
 - ❖ Amendments to the DMF. The types of information to be submitted in an amendment include:
 - any change or addition to the technical information, adequately cross-referenced to the date(s), volume(s), section(s), and/or page number(s) affected.

- any change in authorization related to specific customers
- any change in holder name or ownership of the DMF or a change in the agent name or address. Such changes should be reported as separate amendments.
- ❖ an annual update of the DMF containing:
 - a list of all changes and additional information incorporated into the DMF since the previous annual report on the subject matter of the DMF. If the subject matter of the DMF is unchanged, provide a statement that the subject matter of the DMF is current. Note that the annual update is not intended for reporting changes to the DMF. Such changes should be reported as separate amendments.
 - a list of all persons authorized to make reference to the DMF, identifying by name (or code) the information that each person is authorized to incorporate and give the location of that information by date, volume, and page number. If the list is unchanged on the anniversary date, submit a statement that the list is current.
 - identification of any party whose authorization has been withdrawn

Sincerely,

Sharon L. Brownell
Public Health Analyst
Manager of Drug Master Files
Office of Business Processing Services
Records Repository Team

CC: