DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

DMF ACKNOWLEDGEMENT LETTER

COSTER TECHNOLOGIE SPECIALI S.P.A.
Attn: ANDREA RAINERI
VIALE TRENTO, 2 - 38050 CALCERANICA AL LAGO
TRENTO - ITALY

Dear ANDREA RAINERI,

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

DMF Number Assigned:	26960
Date of Submission:	02/25/2013
DMF Type:	III
Subject:	20MM AEROSOL VALVES as manufactured in TRENTO, ITALY
Holder:	COSTER TECHNOLOGIE SPECIALI S.P.A.
Submitted by:	COSTER TECHNOLOGIE SPECIALI S.P.A.
Agent:	NONE

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

Your DMF will be reviewed only in connection with a New Drug Applications, Abbreviated New Drug Application, Investigational New Drug Application, Biological License Application, New Animal Drug Application, Abbreviated New Animal Drug Application, Investigational New Animal Drug Application, or DMF it is intended to support.

You are 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.

See http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/default.htm.

You are expected to:

- Adhere to the statement of commitment you have provided.
- Provide to the FDA by submission to the DMF in two copies.

- Letters of Authorization (LOAs) granting permission to a third party (authorized party) to reference the DMF and for FDA to review the DMF. Listing an authorized party in the Annual Report (see below) is not sufficient to authorize that party to reference the DMF. Submission of a copy of the LOA to the authorized party without submitting two copies to the DMF is also not sufficient to authorize that party to reference the DMF.

  - If you had submitted an LOA without the DMF number with the original submission, please resubmit the LOA with the DMF number.

- Amendments, Annual Reports and Letters of Authorization to the DMF and the types of information to be submitted may be found at the DMF Web Site under http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/default.htm

- Annual Reports to the DMF containing:

  - Date(s) of the amendment(s) reporting changes submitted since the last Annual Report or the original DMF filing date, whichever is most recent.

  Or

  - A statement that no amendments have been submitted since the last Annual Report or the original DMF filing date, whichever is most recent.

  AND

  - A complete list of all parties authorized to make reference to the DMF, identifying by name, reference number, volume, date, and page number the information that each person is authorized to incorporate

  Or

  - A statement that no changes have been made to the list of Authorized Parties since the last Annual Report or the original DMF filing date, whichever is most recent.

  Or

  - A statement that there are no Authorized Parties.

  AND

  - List of all parties whose authorization has been withdrawn

Submissions containing multiple types of information e.g. administrative changes, an annual report, or changes in technical information should specify the different types of information in the header in the cover letter.