



DMF 28032

**DMF ACKNOWLEDGEMENT-REGULAR**

EMILIO CASTELLI S.A.S.  
Attn: MR. GIOSUE CASTELLI,  
LEGAL REPRESENTATIVE  
VIA PER CERRO  
2-20025 LEGNANO (MI), ITALY

Dear Mr. Giosue Castelli,

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

**DMF Number Assigned:** 28032  
**Date of Submission:** FEBRUARY 18, 2014  
**DMF Type:** IV  
**Subject (Title):** SUGAR SPHERES NF as manufactured in BOVISIO MASCIAGO (MB), ITALY  
**Holder:** EMILIO CASTELLI S.A.S  
**Submitted by:** EMILIO CASTELLI S.A.S  
**Agent:** NONE

All subsequent correspondence to this DMF should be identified with the information as provided above and, if in paper, should be submitted in duplicate to the following address:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Central Document Room  
Drug Master File Staff  
5901-B Ammendale Road  
Beltsville MD 20705-1266

Electronic submissions on disc should be submitted in an eCTD format to the same address. Electronic submissions can also be submitted through the Electronic Submission Gateway.

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 when a Letter of Authorization is submitted to the DMF.

You are responsible for compliance with 21 CFR314.420. See "The Guideline for Drug Master Files" <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/ucm073164.htm>