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0862 '02 FEB 13 P2:08

February 11, 2002

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm 1061  
Rockville, MD 20852

**Subject: Response to Draft Guidance for Industry on: Integration of Dose Counting Mechanisms into MDI Drug Products; Availability, (Federal Register, Tuesday, December 11, 2001, Docket # 01D-0510)**

To Whom It May Concern:

Novartis Pharmaceuticals Corporation, East Hanover, NJ in conjunction with Novartis Pharma AG, Basle, Switzerland has reviewed the above cited draft guidance and has the following comments and or observations:

#### General Comments

Novartis welcomes the initiative of the FDA to encourage industry to establish ways of easily tracking the remaining number of doses in Multi-dose inhalers. There is certainly a need in this area. However, it is felt that the current draft is perhaps kept too general with little guidance on what the FDA reviewers would actually like to see in submissions of new MDIs.

Furthermore, we suggest that reference is made to "dose counter / dose indicator" rather than just to "dose-counter". To our knowledge, most of the dose counting mechanisms currently under development for MDIs do not foresee a reading by single actuation, but rather count in multiple units of e.g. 10 or 20. The FDA itself seems to be thinking in the direction of dose-indication as an option to dose-counting by allowing color-coding as one way of indicating the remaining doses in an MDI (Section III A.).

#### Specific Comment

In Section III B. it is indicated that "*The reliability of dose-counters should be established during development under in-vitro-testing ....., as well as clinical use studies.....to obtain information on the technical function....*". We would like the FDA to clarify that they consider this type of

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studies as "**ergonomic studies**" and not as clinical studies were they would also like to see clinical efficacy data.

Thank you for the opportunity to comment. If you have any questions, please contact me at (973) 781-7005.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Clark". The signature is fluid and cursive, with a large initial "R" and a long, sweeping underline.

Robert J. Clark  
Chemistry, Manufacturing and Controls  
Drug Regulatory Affairs

Comments provided in duplicate and sent electronically to  
<http://www.fda.gov/dockets/ecomments>

ORIGINAL  
SUBMISSION



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Drug Regulatory Affairs

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February 11, 2002

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SUBMISSION**

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