



Pfizer Consumer Healthcare

February 27, 2002

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

RE: Rolaid[®]
SUBJECT: Exemption from 21CFR201.66 Request for Deferral of Compliance Time
Docket No. 98N-0337

Dear Sir or Madam:

Pfizer Consumer Healthcare currently markets Rolaid[®] in two convenience roll packages of 10-count (Regular) roll and a 12-count (Extra Strength) roll. One roll of Rolaid[®] contains the maximum daily dose of antacid permitted by the Antacid Over-the Counter (OTC) drug monograph. Pfizer has been marketing this shelf-keeping unit (SKU) for 30 years at the front end of retailers and convenience stores. Our current labeling text is provided as Attachment 1. The current label does not have enough space to accommodate the Drug Facts format. We are evaluating several labeling options to try to develop a compliant label.

We are aware of the recent 6-month deferral for compliance time granted by FDA to McNeil Consumer Healthcare for Extra Strength Tylenol[®] PM Caplets in a 10-count vial. Also, we are aware of the petition from Lil' Drugs for an exemption from labeling requirements for convenience-size packages. We believe that Rolaid rolls (10 and 12 count) should also qualify as a convenience-size package that would fit into the definition of a convenience-size package. Pfizer Consumer Healthcare intends to comment on the definition of a convenience-size package at the appropriate time.

Implementation of a revised label on the Rolaid[®] roll will require additional compliance time. Therefore, we are submitting this request for additional time (7 months) beyond the May 16, 2002 compliance deadline to ensure that we can acquire, install, and validate the equipment that is necessary to produce, on a reliable, repetitive basis, a "compliant" roll package. The label and equipment are innovative technologies and they require sufficient development time to master the interface between equipment and material. We currently are in the process of identifying from several technological possibilities what is the best label option for Rolaid[®] roll.

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As the agency is undoubtedly aware, activities involving package design, equipment design and acquisition, and packaging line validation expend considerable resources. Based on our company's historical experience in designing and implementing new packaging options, the timeline for implementation of the wrap-around label is as follows:

Activity	Timing
Modify Packaging Equipment/Process	1 st Quarter 2002
Conduct Preliminary Packaging Trials	1 st Quarter 2002
Finalize Label Specifications	2 nd Quarter 2002
Conduct Second Packaging Trial/ Modify Equipment if necessary	2 nd Quarter 2002
Final Packaging Validation	2 nd Quarter 2002
Initiate Full Scale Production	3 rd Quarter 2002
Start to Ship	4 th Quarter 2002

Our request for a 7-month (to December 21, 2002) deferral in complying with the May 16, 2002 deadline for compliance with Drug Facts labeling is based on the estimates in the above table.

If there are any questions, please contact me at 973-385-5419.

Sincerely,



Robert Kohler
Regulatory Affairs

cc: (Letter only) C. Ganley, MD (HFD-560)
Attachment

Attachment 1

