



McNeil Consumer Healthcare, 7050 Camp Hill Road, Fort Washington, PA 19034-2299 (215) 273-7000

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Docket No. 98N-0337
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Application for Exemption from 21CFR201.66
Request for Deferral of Compliance Time

Dear Sir or Madam:

McNeil Consumer Healthcare currently markets Imodium® AD Caplet in a 2 count polyester/polyethylene/foil pouch. This product is approved under NDA 19-860. McNeil has been marketing this shelf keeping unit (SKU) for approximately 10 years. Current non-**Drug Facts** labeling text is provided as Attachment 1.

Due to the limited amount of space that is available for labeling on this pouch SKU, we have developed a booklet style pouch to accommodate implementation of **Drug Facts**. The labeling text in booklet format is provided as Attachment 2. The pages of the booklet pouch can be opened by the consumer, thus providing complete labeling information.

Actual use of this booklet pouch may require additional compliance time for implementation. Therefore, we are submitting this request for additional time (6 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" booklet pouch package. The pouch is an innovative package technology and requires sufficient development time to master the interface between equipment and material.

As the agency is undoubtedly aware, activities involving new package design, equipment 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 booklet pouch follows:

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<u>Activity</u>	<u>Timing</u>
Order and build equipment	4 th Quarter 2001 & 1 st Quarter 2002
Obtain equipment	1 st Quarter 2002
Install and validate equipment	2 nd Quarter 2002
Finalize booklet pouch specifications	2 nd Quarter 2002
Line testing and resolution of potential material issues	2 nd Quarter 2002
Packaging validation	3 rd Quarter 2002
Initiate production	3 rd Quarter 2002
Start to ship	4 th Quarter 2002

We would appreciate your review of this deferral request for additional compliance time. If there are any questions, please contact me at 215-273-7878.

Very truly yours,

McNEIL CONSUMER HEALTHCARE



Paula J. Oliver
Senior Director
Medical and Regulatory Science

cc: (Letter only) C. Ganley, MD (HFD-560)
W. Ellenberg, Ph.D. (HFD-560)
NDA 19-860

Attachments

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