



QUALITY SERVICES DEPARTMENT
1440 OLYMPIC DRIVE • ATHENS, GEORGIA 30601-1645 • (706) 353-4400
FAX (706) 353-3205

2003 3 04 JUL -E 19:47

July 2, 2004

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

Re: Docket No. 2003D-0571; Draft Guidance for Industry on Drug Substance Chemistry, Manufacturing and Control Information; 69 Federal Register 929 (Jan 7, 2004)

Dear Sir/Madam:

This letter is in support of the comments on the above draft guidance submitted by Betsy Fritschel on behalf of Johnson & Johnson. We at Noramco, Inc. worked closely with Ms. Fritschel on these comments and are in full agreement. We also actively participated in and fully agree with the comments submitted by PhRMA.

We are concerned about the additional detail being requested by the draft guidance. We feel this additional detail requirement would add additional work and time to filing preparation and FDA review without adding value.

PhRMA has suggested that the entire approach regarding Attachment 1 and 2 be reconsidered. We completely support PhRMA regarding this approach.

Please contact me if you have any questions.

Sincerely yours,

Jamie Moore
Manager, Regulatory Affairs

2003 D-0571

C 20