

PHARMACIA

1055 '00 NOV -1 A9:12

Jenny Peters
Director
Regulatory Intelligence
Global Regulatory Affairs

Pharmacia
7000 Portage Road
Kalamazoo, Michigan 49001

tel: (616) 833-8141
fax: (616) 833-0512
jenny.l.peters@am.pnu.com

October 31, 2000

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

Re: Docket No. 00N-1449; *Changes to an Approved NDA or ANDA*

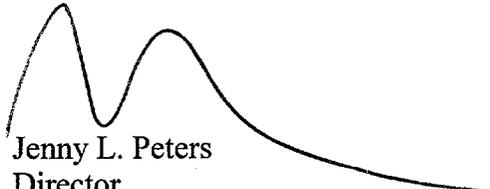
Dear Sir or Madam:

Thank you for this opportunity to comment on the collection of information contained in the guidance for industry entitled "Changes to an Approved NDA or ANDA."

Our remarks are attached. Should any clarification of our input be required, please don't hesitate to contact me at (616)-833-8141.

Sincerely,

Pharmacia Corporation



Jenny L. Peters
Director
Regulatory Intelligence
Global Regulatory Affairs

00N-1449

01

In the Federal Register notice of 7 September 2000, FDA invites comments on the following questions:

1. whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility;
2. the accuracy of FDA's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. ways to enhance the quality, utility, and clarity of the information to be collected; and
4. ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Regarding question 1, Pharmacia believes that FDA's primary responsibility is to assure the quality, safety, and efficacy of the US drug supplies. As such, the collection of information relative to post approval changes is a worthwhile task for the FDA.

FDA estimates of the time required for drug sponsors to compile and submit such information (question 2) are lower than our estimates. The following table summarizes the procedures performed at Pharmacia and the estimated time that Regulatory Affairs personnel and others spend in compiling, reviewing, and assembling information for both changes being effected (CBE) and prior approval supplements (PAS).

	CBE (hours)	PAS (hours)
Submit proposal	16	16
Minutes of conference calls/ Contact reports	2	4
Batch analyses	½	1
Stability reports	32	48
Supporting documentation	32	48
Cover Letter	4	4
Sub-total	86.5	121
Regulatory Operations & Final Review (half of sub- total)	43	60.5
Total	129.5	181.5

Based on these estimates, we feel that the actual amount of time spent on a PAS is closer to 200 hours. Similarly, a CBE takes closer to 150 hours.

We estimate that time spent compiling, assembling, and reviewing annual reports is 50 hours.

Regarding question 3, we recommend that the FDA summarize reporting requirements in a tabular format in addition to the discussion provided in the guidance document. If possible, flow charts should be developed to aid sponsors through the process of determining the proper reporting mechanism.

We would also like to comment that it would be helpful to have easy access to such things as inks used in CDER-approved products and GMP status.

Attach the Airborne Express Shippers Label within the dotted lines.

TYPE OR PRINT
 THIN U.S. ONLY
 BIANCHI

FROM

18284108

PHARMACIA CORPORATION
 BLDG 295
 7000 PORTAGE RD
 KALAMAZOO MI 49001

TO

Terry Peters 416 833 8141
 Food and Drug Administration
 5030 Fishers Lane rm. 1061
 Rockville MD 20852
 Dockets Management Branch

Payment Origin 5108322225

Bill to: Receiver 3rd Party

Paid in Advance

AIRBORNE EXPRESS

Billing Reference will appear on invoice. 01234-0425

# of Pkgs	Weight (LBS)	Packaging Letter Express	One box must be checked Express Pack	Other Packaging
1	1	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Special Instructions

SAT HAA LAB

5 1 0 8 3 2 2 2 2 5

EXP
(Letter - 150 lbs)

NAS
(Letter - 5 lbs)

SDS
(Letter - 150 lbs)



MLDA4X

PEEL BACK FROM

United States Shipping

1. Complete applicable white sections of the U.S. Airbill. Sign and

Limitation on Contents

The maximum acceptable contents of a Letter Express is forty (40) 2 1/2 x 11 pages. If the gross weight of the contents, envelope and