Kacuba, Alice

From: Kacuba, Alice
Sent: Thursday, January 29, 2009 3:53 PM
To: 'sibylle.jennings@novartis.com'
Cc: Cottrell, Christy L.
Subject: NDA 22334: Information request

Importance: High

Hi,

Then Stats reviewer has the following Information Request. Please submit an amendment ASAP.

Thank you.

Alice
Alice Kacuba, RN, MSN, RAC
Chief, Project Management Staff
Division of Drug Oncology Products
Office of Oncology Drug Products
OND/CDER/FDA
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alice.kacuba@fda.hhs.gov

Please explain the reasons for discrepancy between the following two tables. The first table is constructed based on a_anp dataset in the analysis folder and the second one from anp dataset in the listing folder. Both datasets used are from September 30, 2008 submission (SN 011).

Table 1: Antineoplastic Therapies for Cut off Date 28 Feb 2008 (Based on Analysis Data)

Therapy type	Number of patients with ANP	
	RAD001	Placebo
Missing	18	15
Chemotherapy	12	0
Hormone therapy	0	1
Immunotherapy	8	2
Anticonvulsant	11	1
Hepatic chemoembolization	14	7
Targeted therapy	54	12
Other	5	4
All	96	35

Table 2: Antineoplastic Therapies for Cut off Date 28 Feb 2008 (Based on Listing Data)

Therapy type	Number of patients with ANP	
	RAD001	Placebo
Missing	18	15
Chemotherapy	13	1

Hormone therapy	0	1
Immunotherapy	10	2
Anticonvulsant	15	8
Hepatic chemoembolization	1	0
Targeted therapy	60	15
Other	5	6
All	103	41

Tracking:	Recipient	Read
	'sibylle.jennings@novartis.com'	
	Cottrell, Christy L.	
	Chattopadhyay, Somesh	Read: 1/29/2009 3:54 PM

APPEARS THIS WAY ON ORIGINAL

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/s/

Alice Kacuba
1/29/2009 03:58:46 PM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

REQUEST FOR CONSULTATION

TO *(Office/Division)*: OSE, Sandy Griffith

FROM *(Name, Office/Division, and Phone Number of Requestor)*: Alice Kacuba, DDOP

DATE	IND NO.	NDA NO.	TYPE OF DOCUMENT	DATE OF DOCUMENT
12-30-2008		22-334	labeling for NDA	12-22-08

NAME OF DRUG	PRIORITY CONSIDERATION	CLASSIFICATION OF DRUG	DESIRED COMPLETION DATE
Afinitor	P	Oncology	March 1, 2009

NAME OF FIRM: Novartis

REASON FOR REQUEST

I. GENERAL

- ☐ NEW PROTOCOL
- ☐ PROGRESS REPORT
- ☐ NEW CORRESPONDENCE
- ☐ DRUG ADVERTISING
- ☐ ADVERSE REACTION REPORT
- ☐ MANUFACTURING CHANGE / ADDITION
- ☐ MEETING PLANNED BY
- ☐ PRE-NDA MEETING
- ☐ END-OF-PHASE 2a MEETING
- ☐ END-OF-PHASE 2 MEETING
- ☐ RESUBMISSION
- ☐ SAFETY / EFFICACY
- ☐ PAPER NDA
- ☐ CONTROL SUPPLEMENT
- ☐ RESPONSE TO DEFICIENCY LETTER
- ☐ FINAL PRINTED LABELING
- ☐ LABELING REVISION
- ☐ ORIGINAL NEW CORRESPONDENCE
- ☐ FORMULATIVE REVIEW
- ☐ OTHER *(SPECIFY BELOW)*:

II. BIOMETRICS

- ☐ PRIORITY P NDA REVIEW
- ☐ END-OF-PHASE 2 MEETING
- ☐ CONTROLLED STUDIES
- ☐ PROTOCOL REVIEW
- ☐ OTHER (SPECIFY BELOW):
- ☐ CHEMISTRY REVIEW
- ☐ PHARMACOLOGY
- ☐ BIOPHARMACEUTICS
- ☐ OTHER (SPECIFY BELOW):

III. BIOPHARMACEUTICS

- ☐ DISSOLUTION
- ☐ BIOAVAILABILTY STUDIES
- ☐ PHASE 4 STUDIES
- ☐ DEFICIENCY LETTER RESPONSE
- ☐ PROTOCOL - BIOPHARMACEUTICS
- ☐ IN-VIVO WAIVER REQUEST

IV. DRUG SAFETY

- ☐ PHASE 4 SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
- ☐ DRUG USE, e.g., POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
- ☐ CASE REPORTS OF SPECIFIC REACTIONS (List below)
- ☐ COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP
- ☐ REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
- ☐ SUMMARY OF ADVERSE EXPERIENCE
- ☐ POISON RISK ANALYSIS

V. SCIENTIFIC INVESTIGATIONS

- ☐ CLINICAL
- ☐ NONCLINICAL

COMMENTS / SPECIAL INSTRUCTIONS: The purpose of this consult is request review of the PPI that sponsor revised based on our letter based on your review. The revised PPI is in the edr under the Dec 22, 2008 submission.

Thank you.
Alice Kacuba

SIGNATURE OF REQUESTOR	METHOD OF DELIVERY (Check one)
Alice Kacuba	☒ DFS ☐ EMAIL ☐ MAIL ☐ HAND
PRINTED NAME AND SIGNATURE OF RECEIVER	PRINTED NAME AND SIGNATURE OF DELIVERER

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/s/

Alice Kacuba
12/30/2008 08:10:51 PM

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