DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA New England District Office 1 Montvale Avenue Stoneham, MA 02180 781-587-7500 Industry Information: www.fda.gov/oc/industry	10/1/14,10/2/14, 10/6/14, 10/14/14, 10/16/14
	FEI NUMBER 1000513233

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Timothy P. Clackson, Ph.D. President Research & Development Chief Scientific Officer

FIRM NAME	STREET ADDRESS
ARIAD Pharmaceuticals, Inc.	26 Landsdowne Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Cambridge, MA 02139-4835	Manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1. Not all adverse drug experiences that are both serious and unexpected have been reported to FDA within 15 calendar days of initial receipt of the information.

Specifically, the firm did not submit five reports for Iclusig® within 15 calendar days of initial receipt of the adverse event. For example:

- Case (b) (4) was received on May 16, 2013 reporting that a patient on Iclusig® experienced a thrombus. The report was submitted to the FDA on June 19, 2013.

- Case (b) (4) was received on July 22, 2013 reporting that a patient on Iclusig® experienced pulmonary edema. The report was submitted to the FDA on August 7, 2013.

- Case (b) (4) was received on October 15, 2013 reporting that a patient on Iclusig® experienced pancytopenia. The report was submitted to the FDA on December 20, 2013.

- Case (b) (4) was received on July 1, 2014 reporting a patient on Iclusig® passed away. The report was submitted to the FDA on August 22, 2014.

- Cas (b) (4) sent in information on a patient taking Iclusig® that experienced death on (b) (4) The information was not reported to the FDA until October 25, 2013.

2. Follow-up reports were not submitted within 15 calendar days of receipt of new information concerning post 15-day reports.

Specifically, the firm did not submit two reports for Iclusig® within 15 calendar days of follow up receipt of the adverse event. For example:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Mary McGarry	Mary McGarry, Investigator	10/16/2014

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• Case (b) (4) sent in follow-up information on a patient taking Iclusig® that experienced sepsis and died on (b) (4) The follow-up information was not reported to the FDA until March 13, 2013.

• Case (b) (4) sent in follow-up information on a patient taking Iclusig® that experienced myocardial infarction on (b) (4) The follow-up information was not reported to the FDA until November 14, 2013.

3. Adverse drug experiences that were the subject of post marketing 15-day reports were not promptly investigated.

A. The firm failed to conduct any follow up on two (2) serious and unexpected adverse drug experiences for their marketed drug product, Iclusig®. For example:

• Case (b) (4) reported a patient experienced a stroke (b) (4) The firm has conducted no follow up on this serious unexpected adverse drug experience.

• Case (b) (4) reported a patient was hospitalized after taking Iclusig on (b) (4) The firm has conducted no follow up on this serious unexpected adverse drug experience.

B. The firm failed to promptly investigate adverse drug experiences that were subject of post-marketing 15-day reports for their marketed drug product, Iclusig®. For example:

• Case (b) (4) reported a patient experienced a cardiopulmonary arrest and died (b) (4) 2013. The firm did not promptly investigate with inquiries to the healthcare provider until August 14, 2014.

4. An NDA Field Alert Report (FAR) was not submitted within three working days of receipt of information concerning a failure of one or more distributed batches of a drug to meet the specifications established for it in the application.

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Specifically, the firm did not submit 4 FARs within three working days of receipt of information. For example:

• FAR 2013032 was reported to the company as a product complaint stating that a foreign tablet was allegedly found in a bottle of 45mg Iclusig on March 20, 2013. The foreign tablet was smaller and debossed with "A5" consequently possible to be Iclusig 15mg strength tablet. The FAR was not submitted to the FDA until March 26, 2013.

• FAR 2013040 was reported to the company as a product complaint stating that the bottle contained 55 tablets of Iclusig 15mg instead of the labeled 60 count on April 1, 2013. The FAR was not submitted to the FDA until April 5, 2013.

• FAR 2013070 was initiated by an Out of Specification (OOS) result for dissolution reported on June 27, 2013. The report was not submitted to the FDA until July 3, 2013.

• FAR20140505 was initiated by an Out of Specification (OOS) result for dissolution reported on April 28, 2014. The report was not submitted to the FDA until May 5, 2014.

5. The firm failed to comply with the Risk Evaluation and Mitigation Strategies (REMS) communication plan established with the FDA for Iclusig®.

Specifically, the firm was required to publish advertisements in professional journals throughout the 2014 year. The firm failed to publish the ads for second and third quarter of 2014 in one Journal as required. The firm failed to publish the ads for the third quarter of 2014 in an additional Journal as required.

6. Procedures describing the handling of written and oral complaints related to drug products are deficiently written. Specifically, the firm does not have any procedures for handling, processing and access complaints that may require the submission of a Field Alert Report.

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	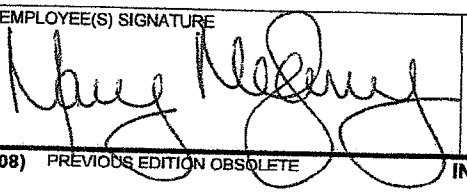	Mary McGarry, Investigator	10/16/2014