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September 30, 2013

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Citizen Petition Regarding Approval and Labeling of Injectable Iron Products

CITIZEN PETITION

Dear Sir/Madam:

On the behalf of our client, Luitpold Pharmaceuticals, Inc., Shirley, New York ("Luitpold"), the undersigned submits this Citizen Petition under the Federal Food, Drug, and Cosmetic Act ("FFDCA"), and 21 C.F.R. § 10.30, to request the Commissioner of Food and Drugs to require that any New Drug Application ("NDA") (or supplement to a NDA) of any injectable form of iron for the treatment of iron deficiency anemia ("IDA") outside of Chronic Kidney Disease ("CKD") be approved only if the clinical studies supporting such approval contain objectively and prospectively derived data that the patients in the pivotal clinical study or studies are intolerant to or have had an unsatisfactory response to oral iron.

A. Action Requested

The undersigned petitions the Commissioner to request that the Food and Drug Administration ("FDA" or "the Agency") approve NDAs (or supplements to NDAs) of injectable iron products for treatment of IDA outside of CKD:

- Only if the approval is based on pivotal clinical studies that include a necessary run-in period where patients take oral iron to confirm intolerance to, or unsatisfactory response to, oral iron or similarly prospectively captured data that provides objective evidence the patients in such studies have such conditions.

2013-8416

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FDA-2013-P-1294

Furthermore the undersigned requests that the Commissioner require that:

- any injectable iron product be contraindicated for use in patients with previous history of allergic reaction to iron products if the pivotal study or studies submitted for approval of such a drug product excluded such patients; and

- any injectable iron product be contraindicated for use in patients with allergies to two or more classes of drugs if the pivotal study or studies submitted for approval of such a drug product excluded such patients.

B. Statement of Grounds

1. The Agency Should Not Approve an Injectable Iron Product for Treatment of IDA Outside of CKD Unless the Applicant Submits Objectively Derived Data that the Patient Population Studied is Intolerant to Oral Iron or Has Had an Unsatisfactory Response to Oral Iron

a. Background

On July 25, 2013, the FDA approved NDA 203565 for the product Injectafer® (ferric carboxymaltose injection). The approved indications for the product[1] are:

> Injectafer is an iron replacement product indicated for the treatment of iron deficiency anemia in adult patients:
>
> - Who have intolerance to oral iron or have had an unsatisfactory response to oral iron;
>
> - Who have non-dialysis dependent chronic kidney disease[2]

Injectafer® is the first injectable iron product approved by FDA that is indicated to replace iron in patients with IDA outside of CKD.

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[1] *See* approved package insert for Injectafer®. (Exhibit 1).

[2] This Petition does not address issues related to use of injectable iron product in CKD patients with IDA. FDA did not require Luitpold to have an oral iron run-in period for the study in the CKD population.

The clinical study that supported the approval of Injectafer® for treatment of IDA outside of CKD is reported on in the article by Onken J.E., et al, entitled "A multicenter, randomized, active controlled study to investigate the efficacy and safety of intravenous ferric carboxymaltose in patients with iron deficiency anemia" published in *Transfusion,* doi: 111/trf.12289, 2013. A copy of the article is attached as Exhibit 2. The design of this study, as required by the Agency, included a required 14 day run-in period to allow for inclusion into the study of patients who had either an unsatisfactory response to oral iron or who did not tolerate oral iron during the 14 day run-in period based on objectively and prospectively derived data. As described therein:

> **Eligibility criteria, randomization, and study medication**
>
> Consenting patients at least 18 years of age who had a screening hemoglobin (Hb) value of not more than 11 g/dL with a ferritin level of not more than 100 or not more than 300 ng/mL when transferrin saturation (TSAT) was not more than 30% and who met all other eligibility criteria .... were given a 14-day run-in of oral ferrous sulfate, 325 mg three times daily. All participants returned on Day 7 of the run-in phase to assess compliance (via pill counts) and tolerance of oral iron. Participants who experienced severe diarrhea, constipation vomiting, or abdominal pain with oral iron were withdrawn from the run-in. Those who experienced other side effects were instructed to decrease the oral iron doses to 325 mg once daily for the balance of the run-in.
>
> Study participants who responded adequately to oral iron during run-in (Hb increase ≥1 g/dL) were not randomized. Participants who had a Hb level measurement of less than 12 g/dL after run-in and either an inadequate response to oral iron (i.e., Hb level increase <1 g/dL/14 days, Cohort 1) or an inability to tolerate oral iron (Cohort 2) were randomly allocated by an interactive voice response system to Group A or B (Cohort 1) or Group C or D (Cohort 2) as described below.....

> **Cohort 1**
>
> Subjects who 1) exhibited unsatisfactory response to a 14-day run-in of oral iron (i.e., Hb increase <1 g/dL from baseline despite ≥67% compliance based on pill count), 2) had ferritin and TSAT values within inclusion criteria ranges, and 3) met none of the exclusion criteria were randomly assigned in a 1:1 ratio either to receive IV FCM (15 mg iron/kg) for a maximum dose of 750 mg on Days 0 and 7 (Group A) or to continue oral iron 325 mg three times a day for an additional 14 days (Group B). Subjects were stratified according to underlying etiology of IDA (HUB, gastrointestinal disorders, or other), baseline Hb (≤9, 9.1-10.0, ≥10.1 g/dL), and baseline cardiovascular risk (category 0-1 or 2-3 per Framingham model).
>
> **Cohort 2**
>
> Participants who tolerated oral iron poorly or for whom oral iron was deemed inappropriate, but who otherwise satisfied the entry criteria, were randomly assigned in a 1:1 ratio to receive either IV FCM according to criteria described above (Group C) or other IVSC preparation....

The requirement for the oral iron run-in period was the result of an Agency requirement imposed on Luitpold that, to obtain approval of the indication, the clinical study needed to identify the relevant patient population that would be treated. As noted in comments made to Luitpold during development of the protocol for the clinical study:

> "Identification of the potential market population was noted as important to design of the major clinical studies."[3]

The Agency was adamant that, given the safety risks with injectable iron products, Luitpold had to provide objective data and evidence providing a rationale for inclusion of patients in the trial.

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[3] *See* FDA Memorandum of Meeting Minutes, Meeting of September 30, 2008, dated October 6, 2008, IND 63,243. (Exhibit 3).

As stated by the Agency:

> "In comments regarding the protocols we indicated that documentation providing justification (eg., specific criteria) for placing a patient into any of these classes would need to be collected and evaluated (ie., a marked check box is not enough)."[4]

The Agency had consistently informed Luitpold that to prove safety and efficacy in the population of patients identified as "intolerant to oral iron" or "a poor responder to oral iron" subjective data would not suffice and that objective data had to be developed. As stated by the Agency:

> "The qualifying question for history of oral iron should not only be yes/no. Documentation needs to be provided to support an assessment of intolerance and/or "unsatisfactory clinical response."[5]

Or as stated in other feedback:

> "Within all your clinical protocols, provide a specific definition for "oral iron intolerant" or identify the criteria that establish a patient as "oral iron intolerant." Additionally, also clearly define the following phrases, "poor responder to oral iron" and "unsatisfactory response to oral iron" or variations upon these phrases. We are concerned that patient assessments using these phrases and concepts may be unacceptably subjective and therefor importantly limit the quality of your studies, the interpretation of the study results and the usefulness of the data from the studies."

See Letter to IND 63,243 dated August 25, 2008. (Exhibit 6).

Furthermore, the Agency addressed the concern that proof was needed that poor responders to oral iron to be included in the trial of Injectafer® needed to reflect actual poor responders, not patients who had not complied with an oral iron regimen. Demonstration of

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[4] *See* Agency Feedback communication, dated September 23, 2008, IND 63,243. (Exhibit 4).
[5] *See* Agency Feedback communication, NDA 22-054, dated March 25, 2008. (Exhibit 5).

compliance to oral iron during the run-in period was considered essential by the Agency. As stated in a letter dated September 26, 2006:

> Note that a between treatment difference in success that appears to be due to lack of compliance will not be interpreted as a demonstration of drug efficacy.

See Exhibit 6. The Agency stated that compliance needed to be demonstrated because "[i]f patients were compliant with oral iron, maybe they would not need an invasive treatment (Ferinject)."[6] *See* Luitpold Meeting Minutes, Meeting dated March 9, 2007, page 2 (Exhibit 7). As further detailed about the need to define "unsatisfactory response to oral iron", the Agency stated: "... the definition should incorporate a minimal degree of compliance ...". *See* FDA Meeting Minutes, Meeting dated November 20, 2008, item 2, page 2. (Exhibit 8). To address this concern, the pivotal trial had detailed requirements to demonstrate compliance with the oral iron regimen. *See* pages 3-4, above.

As early as 2005, the Agency expressed its concern that the population studied had to be one in which oral iron was given a chance to work and did not work in those patients, whether due to poor response or tolerance. *See* FDA letter to IND 63,243 dated April 29, 2005 (Exhibit 9) and Luitpold's Minutes of a teleconference of May 20, 2005 discussing that letter. (Exhibit 10).

[6] Ferinject® was the proposed trademark for the product at that date; it was subsequently changed to Injectafer®.

The need to define intolerance was also an issue. As stated clearly in a teleconference dated September 30, 2008, by Dr. Richard Pazdur, Office Director:

> "You need to define intolerant. Collect historical data. Give the patient a month of oral iron, document why the patient refuses to take oral iron (i.e., GI distress, not feeling like it, and refusal to take it, etc.). Document the course given (i.e., what is the oral iron, how many doses, and decision not to give.) Then give them your product as a follow up product."

See Exhibit 11. The Agency emphasized that the definition of intolerance needed to be specific and rigorous. As stated by the Agency:

> "The definition of "intolerant to oral iron" is not acceptable in that it does not specify the types of adverse events typical of oral iron-intolerance and it appears to include patients who have resolution of intolerance following a decrease of the oral iron dose. We request more specification of the types of adverse events that may prompt discontinuation of oral iron. These adverse events may include documented severe diarrhea, vomiting, constipation, and abdominal pain that prevent further oral iron treatment."

See FDA Feedback Letter, November 17, 2008, item 2, page 2. (Exhibit 12).

As a result of the Agency's concern that it was necessary to collect data to identify on an objective and prospective basis the patient population of poor responders and those intolerant to oral iron, Luitpold developed the 14 day oral iron run-in period as this was the only method to conduct a study to collect objective, not subjective, data that the proper population to support the indication would be studied and to address the requirements of the Agency. For patients who had an unsatisfactory response to oral iron, compliance with oral iron regimen in the run-in period was documented so that it was objectively clear that lack of response was due to lack of effect and not lack of compliance. Only patients who actually did not respond to oral iron were

entered into Cohort 1. Documentation of intolerance was required as condition of entry into Cohort 2. As is clear from the design of the Onken study discussed above, Luitpold did collect objective prospectively derived data such that only patients who objectively met the definitions of intolerant to or poor responders to oral iron were included in its pivotal clinical trial supporting approval of Injectafer®

b. Potential Approval of Feraheme® for the Same Indication

It has recently come to the attention of Luitpold that approval of another injectable iron product for the same indication (and same active moiety-iron) is being sought apparently without a similar demonstration that the patient population studied objectively reflects patients intolerant to or poor responders to oral iron. AMAG Pharmaceuticals, Inc. has filed a Supplement to its NDA (NDA 022180) for Feraheme® (ferumoxytol injection) to obtain approval of the same indication for treatment of IDA outside use in adult CKD patients.[7]

The pivotal trial to support approval in this indication was recently published electronically in the *American Journal of Hematology*. *See* Vadjan-Ray S, Strauss W., Ford D, Bernard K, Boccia R, Li J and Allen LF. Efficacy and safety of IV iron feromoxytol for adults with iron deficiency anemia previously unresponsive to or unable to tolerate oral iron. *Am. J Hematol,* Accepted Article doi: 10.100 2/ajh 23582 (*See* Exhibit 14). As discussed in the article, the patient population included:

> Eligible patients were men and women ≥18 years of age with a history of IDA, defined as a hemoglobin (Hgb) level <10.0 g/dL

[7] *See* Exhibit 13. Note that FeraHeme® is already approved as an iron replacement product for treatment of IDA in CKD patients.

> and a transferrin saturation (TSAT) <20%, and a **history of unsatisfactory oral iron therapy or in whom oral iron could not be used**. Serum ferritin was not utilized as an entry criterion, because, although indicative of iron deficiency if low, eg., <100 ng/mL, it is an acute-phase reactant and may be artifactually elevated in the face of inflammation. Patients were not eligible for participation if they had a history of allergy to IV iron, a Hgb level ≤7.0 g/dl[1], serum ferritin >600 ng/mL, known causes of anemia other than iron deficiency, active infection, hematologic malignancies, were on dialysis or had an estimated glomerular filtration rate <30 mL/min/1.73 m^2, or were pregnant, intended to become pregnant, or were breastfeeding. Patients who received another investigational agent or IV iron therapy within 4 weeks of screening or who had received oral iron therapy or blood transfusion within 2 weeks prior to screening were also excluded.

(Emphasis added). There is no further discussion of what satisfied the criteria for "a history of unsatisfactory oral iron therapy or in whom oral iron could not be used". One would presume if that it were more than a mere check-off, the article would have clearly indicated what the objective criteria were that allowed a demonstration of intolerance to oral iron or proof of a prior inadequate response.

The other clinical trial which, on information and belief, has been submitted to support approval of Feraheme® for this indication has not yet been published; however, an abstract from the 2012 ASH® Annual Meeting and Exposition is available. (*See* Exhibit 15). The only item of relevance to the patient population studied in the abstract is the statement: "The study was designed to demonstrate non-inferiority and consisted of a 14 day screening period, treatment and a 5 week follow-up period." No details were provided as to what the screening period consisted of and whether objective data were the basis of randomization of patients into the trial.

Again, one would assume that if objective data were collected, it would have been described as part of the study design.

c. Agency Approval of Feraheme® or any Other Injectable Iron Product for Use in Treatment of non-CKD IDA Would Constitute Arbitrary and Capricious Action Unless Objective Data is Submitted to Prove the Population Studied Meets Objective Criteria Demonstrating that They Meet the Indication.

If AMAG did not demonstrate the patient population studied in these two trials were intolerant to or had an unsatisfactory response to oral iron through objectively and prospectively derived data collected during a run-in period, the Agency should not approve the supplement to the Feraheme® NDA requesting approval of the indication in this population, nor should approval be granted to any other injectable iron product for the indication without such data. The Agency required Luitpold to collect such data and demonstrate that the patient population it studied objectively met specific criteria to satisfy the Agency that the population included were intolerant to or had had an unsatisfactory response to oral iron. The data was not based on a subjective evaluation of the history of use of a product in a patient, a check-off or other non-objective data, but rigorously and prospectively collected safety and efficacy data demonstrating that only patients meeting the criteria were studied. It was proof of the safety and efficacy in the clinical study in this objectively derived population that served as basis for the approval of Injectafer®.

The approval of Feraheme® or any other injectable iron product for the indication for use as iron replacement product for treatment of IDA in patients intolerant to oral iron and who have had an unsatisfactory response to oral iron should be based on the same rigorous degree of proof

that the patient population studied met the definition and met it based on objective data. To do so otherwise would constitute arbitrary and capricious action by the Agency. *See Bracco Diagnostics, Inc., v. Shalala,* 963 F.Supp. 20 (D.D.C. 1997). As stated therein in deciding that the Agency could not treat similar products in a dissimilar fashion:

> The MBI products and plaintiffs' products all likely meet both the definition of a drug and the definition of a device under the Federal Food, Drug and Cosmetic Act, and the FDA therefore has discretion in determining how to treat them. *See* 21 U.S.C. § 353(g) ("The Secretary shall designate a component of the Food and Drug Administration to regulate products that constitute a combination of a drug, device, or biological product.") What the FDA is not free to do, however, is to treat them dissimilarly and to permit two sets of similar products to run down two separate tracks, one more treacherous than the other, for no apparent reason. Plaintiffs merely maintain that the same tests and studies should be required of each product before it is approved and that that result is impossible so long as the FDA treats one as a device subject to the regimen established by the CDRH and the other three as drugs subject to the more rigorous regimen established by the CDER. The Court agrees. **The disparate treatment of functionally indistinguishable products is the essence of the meaning of arbitrary and capricious.** *See Independent Petroleum Assoc. of America v. Babbitt,* 92 F.3d at 1260; *Doubleday Broadcasting Co. v. FCC,* 655 F.2d at 423. Plaintiffs therefore are likely to succeed on this argument as a matter of law.

(Emphasis added). *See Id,* at 28. In this case, not to require objective data from certain applicants for drugs with the identical active moiety for the same indication that the patient population studied meets the patient population to be treated, while requiring it of another applicant with drug with the identical active moiety for the same indication, would be arbitrary and capricious action by the Agency.

Luitpold therefore requests that the Commissioner not approve any NDA or Supplement to NDA, such as that filed by AMAG, for treatment of IDA in patients intolerant to or who have had unsatisfactory response to oral iron unless the applicant has objectively proven by a run-in period that the patients in the pivotal trial(s) reflect the population to be treated.

2. The Agency Should Require that Use of an IV Iron Product Be Contraindicated in Patients With a History of an Allergic Reaction to IV Iron and in Patients with an Allergy to Two or More Classes of Drugs Unless Clinical Studies Included Such Patients

The clinical trial that supported the approval of Injectafer® for treatment of IDA in patients intolerant to oral iron who had an unsatisfactory response to oral iron had medically appropriate exclusion criteria, but patients who had a prior allergic response to IV iron or multiple drug allergies were specifically and intentionally not excluded.[8] The Agency, during the review of the various protocols for studies of Injectafer®, made it clear that Luitpold should "minimize the exclusion criteria to more appropriately reflect the potential market population." *See* item 7, FDA Feedback Letter, IND 63,243, dated May 26, 2009. (Exhibit 17). *See* also Luitpold's Meeting Minutes of a meeting with the Agency on May 18, 2009, at page 6, where the following discussion was recorded:

> "**SPONSOR**: Last point, the Division indicated that the exclusion criteria may be too long; some discussion may be needed with the Division.
>
> **FDA**: You need to explain why these subjects are excluded. Unless you want all these in your label.
>
> **SPONSOR** Do you want to discuss it here at the meeting?

[8] *See* Exhibit 16, downloaded from the publisher's website.

> **FDA:** No not here. Reconsider each exclusion criteria. It needs to represent criteria to be applied to the marketed drug. Explain why each group of patients was excluded in the pre-marketing situation. Include that in your submission for us to review. We are open to developing this with you."

See Exhibit 18. The Agency made it clear that medical criteria that excluded patients from participation in the pivotal trials could be put in the label. As will be discussed below, the class of patients who are intolerant to/allergic to other IV irons or who have multiple drug allergies are a class that are vulnerable to serious drug reactions, and were not put in the label for Injectafer® because they were included in the studies.

The studies submitted by AMAG to support the approval of Feraheme® in this population, however, excluded such patients. As stated in the Vadjan-Raj article (Exhibit 14):

> Patients were not eligible for participation if they had a history of allergy to IV iron, ...

(*See* pages 5-6). In addition, the study excluded patients with a history of allergic reactions to two or more classes of drug. *See* description of study at www.clinicaltrials.gov, Exhibit 19. The ASH abstract relating to the other study is silent on the issue of whether patients with a prior history of allergic reactions to IV iron or to two or more classes of drugs were excluded; however, it is clear that patients with a prior history of allergic reactions to IV iron in two or more classes of drugs were excluded in this study as well. *See* description of study at www.clinicaltrials.gov. Exhibit 20.

A history of drug allergy is significant in the safety of IV iron products, particularly as to the potential to cause anaphylactoid reactions. As demonstrated in a study by Fishbane et al., of

the safety of IV iron dextran in hemodialysis patients, which analyzed various variables as possible predictors of adverse reactions, including age; sex; history of pulmonary or cardiovascular disease; current use of alcohol; and a history of drug allergy, only a history of drug allergy was found to be predictive of adverse reactions. As stated therein:

> The only variable that was found to be predictive of the development of an adverse event was a history of drug allergy (not including allergy to iron dextran) (odds ratio, 2.4; $P = 0.03$): nine of 27 reactions occurred in patients with a history of drug allergy. In patients with a history of multiple drug allergies (recorded allergy to more than one drug), there was a significantly increased risk of a reaction to iron dextran (odds ratio, 5.5: $P = 0.0004$); six of 27 reactions occurred in patients with multiple drug allergies. The negative predictive value of an absent history of drug allergy was 96% (only 4% of patients with no history of drug allergies developed a reaction to iron dextran). When anaphylactoid reactions were analyzed separately, a history of drug allergy was again a statistically significant predictor (odds ratio, 3.9; $P = 0.04$). Interestingly, three of 10 anaphylactoid reactions occurred in patients with a history of multiple drug allergies. In patients with multiple drug allergies the odds ratio for an anaphylactoid reaction was 4.9 ($P = 0.046$).

See Fishbane S, Ungureanu V, Maesaka JK, Kaupke CJ, Lim V, and Wish J. The safety of intravenous iron dextran in hemodialysis patients. *Am J Kidney* Dis. 28(4): 529-534, 1996. (Exhibit 21).

It should go without stating that a product that has not been proven safe and effective in a patient population should not be used in that population, particularly where it could lead to anaphylactoid reactions. As allergic and hypersensitivity reactions are the most serious known reactions to IV iron product, and which be life threatening or fatal, the labeling for all IV iron products contains either a bolded warning (Injectafer®, Venofer®, Ferrlecit ® and generics and

Feraheme®) or a black box warning (the iron dextran injection products InFeD® and Dexferrum®)[9]

The regulations on prescription drug labeling state the following about when a contraindication is required:

> (5) *4 Contraindications.* This section must describe any situations in which the drug should not be used because the risk of use (e.g., certain potentially fatal adverse reactions) clearly outweighs any possible therapeutic benefit. Those situations include use of the drug in patients who, because of their particular age, sex, concomitant therapy, disease state, or other condition, have a substantial risk of being harmed by the drug and for whom no potential benefit makes the risk acceptable. Known hazards and not theoretical possibilities must be listed (e.g, if severe hypersensitivity to the drug has not been demonstrated, it should not be listed as a contraindication). If no contraindications are known, this section must state "none."

See 21 C.F.R. § 201.57(c)(5). Where hypersensitivity to drug is a known fact, and a product has not been shown to be safe to use in that population based on clinical evidence, its use in that population should be contraindicated. As the studies of Feraheme® excluded patients with prior intolerance to IV iron and a history of allergic reactions to two or more classes of drugs, its use in those patients should be contraindicated in the labeling for Feraheme®.

C. Environmental Impact

This petition qualifies for a categorical exemption from the requirement to submit an environmental assessment under 21 C.F.R. §§ 25.30(h) and 25.31(a).

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[9] *See* inserts attached as Exhibit 22.

D. Economic Impact

According to 21 C.F.R. § 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely,

Peter S. Reichertz
for SHEPPARD, MULLIN, RICHTER & HAMPTON LLP
SMRH:201003515.2

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