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Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20857

RE: Docket 2004P-0070

Dear Sir/ Madam:

Teva Pharmaceuticals USA ("Teva") makes this submission in response to the February 13, 2004 citizen petition and the August 17, 2004 citizen petition filed on behalf of Watson Pharmaceuticals, Inc. ("Watson") by Chesapeake Regulatory Group, Inc. and Frommer Lawrence & Haug LLP, respectively.

The earlier petition requests that FDA not approve any ANDA citing Watson's Ferrlecit® as the reference listed drug unless, *inter alia*, the generic product uses the same manufacturing process as Watson's process for Ferrlecit®. Subsequently, and apparently spurred by the filing of a suitability petition, Watson's agent filed a separate citizen petition which requests that FDA refuse to receive an ANDA citing Ferrlecit® until the FDA establishes guidelines specific to the determination of whether a generic product is the same as Ferrlecit®.

With regard to the initial petition, Teva offers the following comments:

1. Watson can offer no basis to support their claims that a single manufacturing process is necessary to produce an equivalent version of this product. To say this with any certainty, Watson would have to show that **all other** processes produce inequivalent products, which of course they have not done.

Additionally, Watson asserts that, since this molecule is not fully characterized, "it is impossible to determine if two products...are the same." FDA has previously considered and rejected this position when used by other brand manufacturers seeking to thwart lower priced generic competition. FDA and the courts held that absolute chemical identity is not required for generic drug approval and that such a requirement would appear to be contrary to Congressional intent. *Serono Labs v. Shalala*, 158 F.3d 1313, 1320 (D. C. Cir. 1998).

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2. Petitioners cite a brief history of several parenteral iron supplement injectable products which vary in molecular weight and are not rated as therapeutically equivalent. Since these products were not developed to be equivalent, it is not surprising that they vary. This information bears no relevance to the issue at hand, i.e., the development of generic versions of sodium ferric gluconate which are designed to be therapeutically equivalent to Ferrlecit®.

3.a) Petitioner touts that the manufacturing process and equipment used to manufacture Ferrlecit® are nearly 45 years old. Simply because Watson experienced failure at attempts to change aspects of the process, this is not grounds for concluding that Watson's process and equipment are the ONLY means of producing a product equivalent to Ferrlecit®. As petitioner states "Variations in any of these parameters throughout the manufacturing process COULD (emphasis added) result in critical changes to the final product." However, petitioner did not and can not state that variations WILL result in critical changes to the final product.

b) and c) Again petitioner states, and Teva agrees, that physicochemical differences resulting from different methods of production COULD have a negative impact on the efficacy of the product. Teva does not agree that these differences necessarily WILL have such an impact with this product.

4. The adequacy of the physicochemical and structural analysis of any generic version of Ferrlecit® can only be determined by FDA's review of a generic application. Watson's attempts to convince FDA *a priori* that it simply can not be done are actually an indication of how much Watson does not want FDA to have the opportunity to review a scientifically sound generic drug application.

5. Petitioner cites increases in adverse events which correlate to changes in the formulation or ingredient source. While this correlation may or may not be appropriate, Teva does acknowledge that it is probably true that not ALL formulations or processes will yield an equivalently safe and effective product. Teva, however, does not agree that it is only the Watson process and formulation that will yield an equivalently safe and effective product.

6. Petitioners continue to cast doubt on the ability of a generic applicant to produce a pharmaceutically and therapeutically equivalent product with the same physicochemical properties as the brand product. Again, the review of data submitted in the context of a generic application will be the determining factor here.

Since petitioner has done nothing but raise unsubstantiated doubt about the possibility of the development of an equivalent generic version of Ferrlecit® and since petitioner has not adequately demonstrated that Watson's process is the only process that can produce such a product, this petition should be denied.

With regard to the second petition, Teva offers the following comments:

Apparently having realized that the adequacy of data needed to determine if a generic version of Ferrlecit® is equivalent can only be accomplished by the review of data submitted in a generic application, petitioner is now requesting that FDA refuse to receive such an application, thus

avoiding the opportunity for such a conclusion on the part of FDA. Simply for its transparency of intent, this petition should also be denied.

In conclusion, petitioners have raised nothing more than unsubstantiated doubts about the ability of a generic applicant to produce and scientifically establish a generic version of Ferrlecit® as therapeutically equivalent. Anecdotal information, used preferentially to make petitioners' unsubstantiated points, should not be permitted to waste valuable agency time or to slow review and approval of generic applications¹. Therefore, independent of the review of any application for sodium ferric gluconate, the agency has no option but to deny these baseless petitions as they are neither scientifically nor regulatorily sound.

Respectfully submitted,


DAJ

¹ Proposed rule, FR Vol.64, No. 229, 66822-66827 requires “the citizen petition to be based on more than unsupported claims, allegations or general descriptions of positions or arguments.” The proposal also notes that some petitioners have submitted multiple citizen petitions concerning the same subject or product with each petition containing one or few requests. It is noted that these petitions “drain FDA resources both repeatedly and inefficiently”.