AMGEN

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December 16, 2013

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir or Madam:

RE: Docket No. FDA-2011-N-0898: Permanent Discontinuance or Interruption in Manufacturing of Certain Drug or Biological Products, propose rule; 78 Fed. Reg. No 213, 65904

Dear Sir or Madam:

Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its biologics manufacturing expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be the world's largest independent biotechnology company, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential

Amgen is pleased to be afforded the opportunity to provide comments on the *Propose Rule for Permanent Discontinuance or Interruption in Manufacturing of Certain Drug or Biological Products.* We share FDA's concern about the public health impact caused by drug shortages and strive to meet our corporate mission of serving every patient, every time. We fully support efforts to develop effective means to address the causes of these shortages and to minimize their impact and duration when they do occur. Amgen has spent hundreds of millions of dollars in the past several years to minimize the risk of shortages of our drug products.

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These actions include:

- Continued emphasis on CGMP compliance;
- Investments in new technology to optimize our control over processes and to minimize the possibility of contamination and cross-contamination;
- Maintenance of inventory levels commensurate with the risk of market demand fluctuation and potential natural disasters, and
- Ensuring redundant manufacturing capability for our products.

Patients and their families should not need to worry about the availability of appropriate drugs to treat life threatening conditions. This is both an unnecessary and avoidable burden.

Amgen supports the requirements in the proposed rule for advance notification of situations and events that may result in drug shortages of innovative and generic drugs alike. We also applaud FDA's inclusion of biological products, both innovative and biosimilar drugs, within the scope of the proposed rule because these innovative and biosimilar products include many life-saving and life-sustaining products. Advance notification allows FDA to work with all stakeholders and exercise regulatory flexibility to prevent and minimize the impact of drug shortages. Dedicated, hard working individuals at the FDA have partnered collaboratively with industry to prevent and mitigate drug shortages. Actions taken by FDA in the years 2011 through 2013 clearly support the value of advance reporting and collaboration between industry and FDA in the prevention and mitigation of drug shortages.

Even though I completely support the proposed rule, I encourage the Agency to consider some potential unintended consequences of the proposed rule, for example:

- The proposed rule does not specify if the FDA will publish information about *potential* drug shortages. The FDA should carefully consider the unintended consequences that may result if information about potential shortages is made available to the public. This may lead to hoarding by distributors, pharmacies, hospitals and other purchasers and may cause or exacerbate a situation that otherwise could have been manageable. Also under these conditions, patients may not take their medications as prescribed, decreasing the dosage to make the prescribed amount last for a longer time, leading to potentially ineffective course of therapy. Finally, information of an impending shortage may facilitate introduction of counterfeit drugs or drugs from questionable sources into the supply chain.

- When publishing definitions in the final rule, we suggest that FDA take utmost care to ensure the definitions have sufficient clarity to prevent both

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under reporting and over reporting. For many firms that supply drugs to the US market, English is a second language and every attempt should be made to ensure clarity and prevent mis-interpretation. Alternatively, FDA might consider publishing a list of drugs as examples that are included in the two categories to prevent mis-interpretation and to facilitate compliance with the rule.

With regard to the consequences of failure to report an impending drug shortage or discontinuation, we suggest that FDA provide notice of such non-compliance to the major news services as well as posting the information on the FDA web site. In this way, consumers, distributors, and payers will have the knowledge of which companies have not complied with this requirement.

It is Amgen's commitment to work proactively with the FDA to enhance regulatory and compliance systems to prevent drug shortages and to minimize their impact when they do occur. We are supportive of this proposed rule that provides another tool for FDA to use in safeguarding and promoting the public health.

Sincerely,

Martin VanTrieste

Martin VanTrieste, R.Ph.
Senior Vice President Quality

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