AMPHASTAR PHARMACEUTICALS, INC.
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January 8, 2003

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Rm. 1-23
12420 Parklawn Drive
Rockville, MD 20857

**CITIZEN PETITION**

The undersigned submits this petition under 21 C.F.R. 314.161, Determination of reasons for voluntary withdrawal of a listed drug, to request the Commissioner of Food and Drugs to determine the reasons for the voluntary withdrawal of Wyeth-Ayerst's listed drug product, Wydase®, Hyaluronidase Injection USP. The Commissioner is also requested to issue a determination that the discontinued labeling of Wydase® was not withdrawn for reasons of safety and effectiveness. The Commissioner is requested to cause a notice to be published in the Federal Register, pursuant to 21 C.F.R. 314.161(e), relisting Wydase® under authority vested in the Commissioner by 21 C.F.R. 314.162(c).

Wydase® is currently listed as a discontinued drug product in the Electronic Orange Book and in Approved Drug Products with Therapeutic Equivalence evaluations, 22nd Edition. The product was approved prior to January 1, 1982, under application number 006343. In the opinion and to the best knowledge of Amphastar Pharmaceuticals, Inc., there are no unexpired patents for the reference listed product in the Orange Book Database or in Approved Drug Products with Therapeutic Equivalence evaluations, 22nd Edition. and there is no unexpired exclusivity for this product.

In January 2001, Wyeth-Ayerst announced that it would not resume manufacturing Wydase®, allegedly due to manufacturing issues.[1] Since then, Wyeth-Ayerst allocated hyaluronidase injection to physicians and hospitals until the remaining inventory was exhausted. That supply is now gone, and no further product is available. Wydase® (Hyaluronidase Injection USP) has been listed on the current drug shortage list

[1] Center for Drug Evaluation and Research. Drug shortages. Available online at www.fda.gov cder/drug/shortages. Updated on January 6, 2003 (January 6, 2003)

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shortage list, and has been determined as a medically necessary product and will facilitate its manufacture once an appropriate alternate supplier is identified [2,3]

Amphastar Pharmaceuticals, Inc. has located a raw material supplier for hyaluronidase, and has initiated stability testing on both the raw material and on compounded Hyaluronidase Injection, USP. It is the intent of Amphastar Pharmaceuticals, Inc. to file an Abbreviated New Drug Application for Hyaluronidase Injection, USP, either on behalf of itself or on behalf of its subsidiary, International Medication Systems, Ltd. Top do so, it is necessary that the innovator product be relisted, following a determination by the Commissioner that the product and its labeling were not voluntarily withdrawn for reasons of safety or effectiveness.

Amphastar Pharmaceuticals, Inc. requests categorical exclusion from requirements for an environmental impact statement, pursuant to 21 C.F.R. 25.30.

Attached hereto is a true copy of the package insert for Wydase®.

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all the 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.

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[2] Center for Drug Evaluation and Research. Drug Shortages general overview. Available online at www.fda.gov/cder/drug/shortages/presentation/sld001.htm. Updated on July 6, 2001. (accessed on January 23, 2002)

[3] Center for Drug Evaluation and Research. Drug shortages. Available online at www.fda.gov/cder/drug/shortages. Updated on January 6, 2003. (January 6, 2003)