



## Imprimis Statement Regarding Curcumin Emulsion FDA MedWatch Notice

August 7, 2017

SAN DIEGO, Aug. 7, 2017 /PRNewswire/ -- Imprimis Pharmaceuticals, Inc. (NASDAQ: IMMY) today released a statement regarding the FDA MedWatch notification issued on August 4, 2017.



Mark L. Baum, CEO of Imprimis stated, "Imprimis is 100% dedicated to patient safety and regulatory compliance. Imprimis has been successful because we place patient safety and compassion for those we serve above all else. Imprimis facilities are regularly inspected by state and federal officials, including the FDA, and our distinguished quality team looks to all regulators as partners in protecting patients, which is critical for the long-term success of our business."

Baum continued, "We are deeply saddened by the tragic events referenced in the FDA MedWatch notice. However, it is important to clarify that we believe these unfortunate events occurred due to allergic or hypersensitivity reactions to a product these patients likely should never have been administered. We have safely dispensed the referenced curcumin emulsion over 30,000 times without incident. The production and safe dispensing of our products (or any drug product) necessitates compliance with the law by the prescribing doctor. Related to this, there are additional facts that must be disclosed to clarify and more completely and accurately inform the public of Imprimis' connection to these cases."

### Additional Facts Regarding the FDA's MedWatch Notice:

- Imprimis did not receive prescription orders for and did not dispense any product, including our curcumin emulsion, to either of the patients referenced in the FDA MedWatch notice.
- Both cases appear to be situations where, without our knowledge, medical professionals wrote a valid prescription for a specific and appropriate patient, and then summarily used the drug we dispensed, without our knowledge, on a completely different patient.
- Imprimis had no knowledge of the allergy histories of the subject patients.
- FDA testing of the IV bag from the 30 year-old patient revealed "*no drugs or poisons including diethylene glycol [DEG] at a level greater than 0.1% by volume, were identified in the IV bag contents using GC-MS.*" We believe that evidence thus far does not support the 30 year-old patient's death being caused by PEG 40 Castor Oil or DEG.
- PEG Castor Oils are suitable excipients used in both compounding and the pharmaceutical industry and there are multiple examples of commercial injections that are FDA approved for which polyethoxylated castor oils are a component of, such as paclitaxel injection, teniposide injection, docetaxel injection, and cyclosporine injection.
- Imprimis received written documentation from its FDA registered and inspected supplier as to the suitability of its PEG 40 Castor Oil material for use in human compounded products. This documentation, received prior to use of the material, stated specifically, "*We certify that our product, P2404 PEG Castor Oil is manufactured, packaged and held in compliance with 21 CFR, Parts 210 and 211 of the United States Code of Federal Regulations and is suitable for pharmacy compounding use.*"
- According to federal and state regulations, it is permissible for Imprimis (and any other pharmacy) to use curcumin in human drug compounding ([FDA's 503A Category 1 for Bulk Drugs for Use in Compounding](#)).
- Imprimis maintains that the prescriptions it filled for the subject curcumin emulsion vials were valid, labeled properly, and that the curcumin emulsion dispensed was correctly made according to state and federal law.

Baum concluded, "Our employees and our company are dedicated to the wellbeing of the people we serve and would never compromise their health and safety. Part of the foundation of our success is following the law – but we also look for ways to exceed the standards we are regulated by. Following these events, we are reviewing our internal policies and looking for ways to

further improve our procedures. We will also continue to work collaboratively with state and federal regulators and discuss ways to improve regulations so that events like these are prevented."

### **About Imprimis Pharmaceuticals**

Imprimis Pharmaceuticals, Inc. (NASDAQ:[IMMY](#)) is a pharmaceutical company dedicated to producing and dispensing high quality innovative medications in all 50 states. The company's unique business model increases patient access and affordability to many critical medicines. Headquartered in San Diego, California, Imprimis owns and operates production and dispensing facilities located in California and New Jersey. For more information about Imprimis, please visit the corporate website at [www.ImprimisRx.com](http://www.ImprimisRx.com).

### **Safe Harbor**

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Any statements in this release that are not historical facts may be considered such "forward looking statements." Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties which may cause results to differ materially and adversely from the statements contained herein. Some of the potential risks and uncertainties that could cause actual results to differ from those predicted include our ability to make commercially available our compounded formulations and technologies in a timely manner or at all; physician interest in prescribing its formulations; risks related to its compounding pharmacy operations; our ability to enter into other strategic alliances, including arrangements with pharmacies, physicians and healthcare organizations for the development and distribution of its formulations; our ability to obtain intellectual property protection for its assets; its ability to accurately estimate its expenses and cash burn, and raise additional funds when necessary; risks related to research and development activities; the projected size of the potential market for its technologies and formulations; unexpected new data, safety and technical issues; regulatory and market developments impacting compounding pharmacies, outsourcing facilities and the pharmaceutical industry; competition; and market conditions. These and additional risks and uncertainties are more fully described in Imprimis' filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q. Such documents may be read free of charge on the SEC's web site at [www.sec.gov](http://www.sec.gov). Undue reliance should not be placed on forward looking statements, which speak only as of the date they are made. Except as required by law, Imprimis undertakes no obligation to update any forward-looking statements to reflect new information, events or circumstances after the date they are made, or to reflect the occurrence of unanticipated events.

Other than drugs compounded at a registered outsourcing facility, all Imprimis compounded formulations may only be prescribed pursuant to a physician prescription for an individually identified patient consistent with federal and state laws.

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