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Generic Drug Product Development: Solid Oral Dosage Forms

Generic Drug Product Development Solid Oral Dosage Forms Leon Shargel Eon Labs, Inc. Wilson, North Carolina Isadore Kanfer Rhodes University Gralunstown, South Africa

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Working document QAS/08.251 January 2008 RESTRICTED DRAFT PHARMACEUTICAL DEVELOPMENT FOR MULTISOURCE (GENERIC) PHARMACEUTICAL PRODUCTS This draft is based on the concept paper QSM/EC/07.29 "Guideline for pharmaceutical

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The key events in the development of the US generic drug industry after the Hatch-Waxman Act of 1984 are systematically reviewed, including the process of approval for generic drugs, bioequivalence issues including "switchability", bioequivalence for complicated dosage forms, patent extension, generic drug safety, generic substitution and ...

"Development of the generic drug industry in the US after

1 Generic Drugs " Application and Regulatory Review Naiqi Ya, Ph.D. Deputy Director Division of Chemistry IV Office of Generic Drugs Opinions expressed in this presentation are those of the speaker and do not

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