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# 2 Active Pharmaceutical Ingredients

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## INTRODUCTION

Active pharmaceutical ingredients (APIs) are also known in regulatory and pharmacopeial parlance as “drug substances.” Additional terms frequently employed in commerce and the literature are bulk pharmaceutical compound, bulk actives, and “active ingredient.” All terms relate to the same “article.” New chemical entities (NCEs), also termed new molecular entities (NMEs), refer to drug substances that are first to enter the drug regulatory arena under the banner of a New Drug Application (NDA). The term “official substance” is defined in the United States Pharmacopeia (USP) as a drug substance, excipient (frequently termed inactive ingredient), dietary ingredient, other ingredient, or component of a finished device for which the monograph title includes no indication of the nature of the finished form [1]. Official substances are the subject of formal monographs in the USP or The National Formulary. Drug substance (API) monographs grace the USP exclusively. The other official articles noted are in other sections of the compendia. Not surprisingly, the end use of the API is to produce a drug product, which is the final