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- (71) Applicant (for all designated States except US): DOR BIOPHARMA INC. [US/US]; Suite F, 28101 Ballard Drive, Lake Forest, IL 60045 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): CONSTANTINIDES, Panos, P. [US/US]; 95 Berkshire Court, Gurnee, IL 60031 (US). LIANG, Likan [CN/US]; 1022 Thomas Boulevard, Mundelein, IL 60680 (US). JANG, Eun-Hyun [KR/US]; Apartment #313, 124 Callan Street, Evanston, IL 60202 (US).
- (74) Agents: INSOGNA, Anthony, M. et al.; Pennie & Edmonds LLP, 1155 Avenue of the Americas, New York, NY 10036 (US).
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(54) Title: STABILIZED REVERSE MICELLE COMPOSITIONS AND USES THEREOF

(57) Abstract: The invention relates to compositions and methods for drug delivery suitable for promoting the transmucosal absorption of drugs, especially drugs with poor intrinsic bioavailability, such as peptides, proteins, vaccines, and nucleic acids. The delivery system of this invention preferably comprises fatty acid esters and their hydrophilic derivatives that associate with water and other polar solvents to form reverse micelles that are physically stabilized in the presence of gastrointestinal fluid, water, and other hydrophilic solvents. Such stable reverse micelles are formed by suitable mixtures of polymeric or non-polymeric compounds with amphiphiles. Micelles made using these methods undergo phase transformation more slowly resulting in delayed drug release profiles and sustained absorption. When administered as a pharmaceutical to mucosal surfaces following oral ingestion or intranasal administration, therapeutic molecules principally solubilized in the aqueous phase are protected from digestion by mucosal enzymes and other mucosal degradative processes and are taken up by absorptive cell mechanisms and reach appropriate body compartments. The reverse micelle compositions may comprise mono-, di-glycerides and/or their transesterified products containing C6-C12 fatty acids chains, wherein the transesterified products consist of hydrophilic moieties.

**INTERNATIONAL SEARCH REPORT**

International application No.

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**A. CLASSIFICATION OF SUBJECT MATTER**  
 IPC(7) : A61K 9/127, 9/48, 9/20; A61F 13/00  
 US CL : 424/450, 422, 434, 435, 451, 464  
 According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**  
 Minimum documentation searched (classification system followed by classification symbols)  
 U.S. : 424/450, 422, 434, 435, 451, 464

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
 EaAST

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y, P	US 6,485,706 B1 (MCCOY et al.) 26 November 2002. See entire document.	1-77

Further documents are listed in the continuation of Box C.  See patent family annex.

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Name and mailing address of the ISA/US: Commissioner of Patents and Trademarks, Box PCT, Washington, D.C. 20231  
 Facsimile No. (703)305-3230  
 Authorized officer: Liliana Di Nicola-Baron  
 Telephone No. 308-1234/ 1235