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(71) Applicant (for all designated States except US): **FARNAM COMPANIES, INC.** [US/US]; 301 West Osborn Road, Phoenix, Arizona 85013 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **CHEN, Andrew, Xian** [US/US]; 4646 Bryson Terrace, San Diego, California 92130 (US). **KIGIN, Patricia, D.** [US/US]; 10984 East Taos Drive, Scottsdale, Arizona 85262 (US).

(74) Agents: **LIN, Qing** et al.; Seed Intellectual Property Law Group PLLC, Suite 5400, 701 Fifth Avenue, Seattle, Washington 98104-7064 (US).

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- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

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(54) Title: SUSTAINED RELEASE PELLETS COMPRISING WAX-LIKE MATERIAL

(57) Abstract: Sustained release spherical or non-spherical pellets comprising (a) an active ingredient (b) a wax-like agent, and (c) a spheronizing agent are provided. Oral dosage forms comprising said pellets and methods for preparing and using such pellets and dosage forms are also provided.



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INTERNATIONAL SEARCH REPORT

International application No
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A. CLASSIFICATION OF SUBJECT MATTER

INV. A61K9/16 A61K31/135 A61K31/7008 A61K31/522 A01N25/34
A61K9/50

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)
A61K A01N

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 practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	EP 1 527 775 A (EURO CELTIQUE SA [LU]) 4 May 2005 (2005-05-04) paragraphs [0007] - [0011], [0018] - [0023], [0027], [0032]	1-8, 29-50 9-28, 51-58
X A	WO 00/35450 A (EURO CELTIQUE SA [LU]; GOLDENHEIM PAUL D [US]; SACKLER RICHARD S [US];) 22 June 2000 (2000-06-22) page 23, paragraph 4; figure 10; example 10; tables 32,33 page 31, paragraph 2	1-8, 29-50 9-28, 51-58
X A	WO 01/58447 A (EURO CELTIQUE SA [LU]; OSHLACK BENJAMIN [US]; CURTIS WRIGHT [US]) 16 August 2001 (2001-08-16) example 6	1-8, 29-50 9-28, 51-58
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Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
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- *O* document referring to an oral disclosure, use, exhibition or other means
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- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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- *Z* document member of the same patent family

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European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Giménez Miralles, J

INTERNATIONAL SEARCH REPORT

International application No
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	WO 2005/000310 A (EURO CELTIQUE SA [LU]; WALDEN MALCOLM [GB]; HAYES GEOFF [GB]; MOHAMMAD) 6 January 2005 (2005-01-06) claim 20; figures 5,6; examples 2,6,17 -----	1-8, 29-50 9-28, 51-58
A	WO 98/42311 A (TAKEDA CHEMICAL INDUSTRIES LTD [JP]; AKIYAMA YOHKO [JP]; NAGAHARA NAOK) 1 October 1998 (1998-10-01) page 14, last paragraph page 27, paragraphs 2,3 page 29, paragraph 1; examples 1,2,8 -----	1-58
A	WO 92/12633 A (FMC CORP [US]) 6 August 1992 (1992-08-06) example 19 -----	1-58
A	WO 96/01057 A (FUISZ TECHNOLOGIES LTD [US]; CHERUKURI SUBRAMAN R [US]; BATTIST GERALD) 18 January 1996 (1996-01-18) examples -----	1-58
A	WO 03/020243 A (LONGWOOD PHARMACEUTICAL RES IN [US]) 13 March 2003 (2003-03-13) page 20, paragraph 3; example 2 -----	1-58

INTERNATIONAL SEARCH REPORT

International application No.
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Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-8 (part), 9-11, 29-58 (part)

Sustained-release composition in form of pellets comprising a) active ingredient, b) wax-like agent, and c) spheronizing agent; wherein the active ingredient is an analgesic. Dosage form comprising said composition. Method of manufacture. Medical use.

2. claims: 1-8 (part), 12-14, 29-58 (part)

Sustained-release composition in form of pellets comprising a) active ingredient, b) wax-like agent, and c) spheronizing agent; wherein the active ingredient is a dietary supplement. Dosage form comprising said composition. Method of manufacture. Medical use.

3. claims: 1-8 (part), 15-17, 29-58 (part)

Sustained-release composition in form of pellets comprising a) active ingredient, b) wax-like agent, and c) spheronizing agent; wherein the active ingredient is an antiviral agent. Dosage form comprising said composition. Method of manufacture. Medical use.

4. claims: 1-8 (part), 18-20, 29-58 (part)

Sustained-release composition in form of pellets comprising a) active ingredient, b) wax-like agent, and c) spheronizing agent; wherein the active ingredient is an anti-infective agent. Dosage form comprising said composition. Method of manufacture. Medical use.

5. claims: 1-8 (part), 21-24, 29-58 (part)

Sustained-release composition in form of pellets comprising a) active ingredient, b) wax-like agent, and c) spheronizing agent; wherein the active ingredient is an antacid. Dosage form comprising said composition. Method of manufacture. Medical use.

6. claims: 1-8 (part), 25, 26, 29-58 (part)

Sustained-release composition in form of pellets comprising a) active ingredient, b) wax-like agent, and c) spheronizing agent; wherein the active ingredient is a high-dose drug. Dosage form comprising said composition. Method of manufacture. Medical use.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

7. claims: 1-8 (part), 27, 28, 29-58 (part)

Sustained-release composition in form of pellets comprising a) active ingredient, b) wax-like agent, and c) spheronizing agent; wherein the active ingredient is an insect growth regulator. Dosage form comprising said composition. Method of manufacture. Medical use.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2008/055534

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