

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Yang et al.

Examiner: Lee, Edmund H.

Application No.: 10/856,176

Group Art Unit: 1791

Filed: May 28, 2004

Docket: 1199-26

For: POLYETHYLENE OXIDE-  
BASED FILMS AND DRUG  
DELIVERY SYSTEMS MADE  
THEREFROM


Dated: January 14, 2008

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT

Sir:

In response to the Requirement for Restriction, mailed December 14, 2007, a response to which is due January 14, 2008, please amend the above-identified application as follows.

**Amendments to the Claims** are reflected in the listing of claims which begins on page 2 of this paper.

**Remarks** begin on page 6 of this paper.

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

1-27. (Canceled)

28. (Original) A process for making a film having a substantially uniform distribution of components, comprising the steps of:

(a) combining at least one water-soluble polymer comprising polyethylene oxide alone or in combination with a hydrophilic cellulosic polymer, a solvent, and an active component to form a matrix with a uniform distribution of said components;

(b) forming a film from said matrix; and

(c) drying said film,

wherein said film is free of added plasticizers.

29. (Original) The process according to Claim 28, wherein the step of forming a film from said matrix further comprises casting said matrix onto a surface having top and bottom sides.

30. (Original) The process according to Claim 28, wherein the step of drying said film further comprises applying heat to said bottom side of said surface.

31. (Original) A process for making a film having a substantially uniform distribution of components, comprising the steps of:

(a) combining at least one water-soluble polymer comprising polyethylene oxide alone or in combination with a hydrophilic cellulosic polymer, and an active component to form a matrix with a uniform distribution of said components; and

(b) extruding said matrix to form a film,

wherein said film is free of added plasticizers.

32. (Original) The process according to Claim 31, further comprising the step of cooling said extruded film.

33-36. (Canceled)

37. (New) The process according to Claim 28, wherein said at least one water-soluble polymer comprises at least about 20% by weight polyethylene oxide.

38. (New) The process according to Claim 28, wherein said at least one water-soluble polymer comprises up to about 100% by weight polyethylene oxide.

39. (New) The process according to Claim 28, wherein said at least one water-soluble polymer comprises up to about 80% by weight polyethylene oxide.

40. (New) The process according to Claim 28, wherein said hydrophilic cellulosic polymer comprises about 0% to about 80% hydroxypropylmethyl cellulose.

41. (New) The process according to Claim 28, wherein said hydrophilic cellulosic polymer comprises about 0% to about 80% hydroxypropyl cellulose.

42. (New) The process according to Claim 28, wherein said water-soluble polymer comprises said hydrophilic cellulosic polymer in a ratio of up to about 4:1 with polyethylene oxide.

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43. (New) The process according to Claim 28, wherein said at least one water-soluble polymer comprises polyethylene oxide having a molecular weight of about 100,000 to about 900,000.
44. (New) The process according to Claim 28, wherein said at least one water-soluble polymer comprises polyethylene oxide having a molecular weight of about 100,000 to about 4 million.
45. (New) The process according to Claim 28, wherein said at least one water-soluble polymer comprises polyethylene oxide having a molecular weight of about 100,000 to about 300,000 in combination with polyethylene oxide having a molecular weight of about 600,000 to about 900,000.
46. (New) The process according to Claim 28, wherein said at least one water-soluble polymer comprises at least 1mg polyethylene oxide.
47. (New) The process according to Claim 28, wherein said at least one water-soluble polymer comprises no greater than about 200mg polyethylene oxide.
48. (New) The process according to Claim 28, wherein said active component is selected from the group consisting of cosmetic agents, pharmaceutical agents, bioactive agents, and combinations thereof.
49. (New) The process according to Claim 28, wherein said matrix of step (a) further comprises a densifying agent.
50. (New) The process according to Claim 49, wherein said densifying agent is simethicone.

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51. (New) The process according to Claim 28, wherein said matrix of step (a) further comprises a solubility enhancing agent.

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