Title: HERBAL COMPOSITIONS FOR INCREASE AND IMPROVEMENT OF MILK YIELD IN CATTLE

Abstract: The present invention in a preferred embodiment provides for herbal compositions for increase and improvement of milk yield in a subject. The present invention also provides for the methods of preparation and various forms of administration of the said compositions. The said compositions comprise of at least a part of Dioscorea bulbifera.
HERBAL COMPOSITIONS FOR INCREASE AND IMPROVEMENT OF MILK
YIELD IN CATTLE

BACKGROUND:
Obtaining increased yield of milk, more specifically from cattle, has been an important activity from the societal and commercial perspective.

Methods for increase and improvement of milk yield in cattle have been practiced over the years, including administering food supplements, breeding programs, and providing doses of synthetic drugs or hormones.

The synthetic medicines or compositions, and associated enhancement methods can be effective in increasing milk yield, but they pose the threat of side effects and chemical toxicity which can adversely affect a subject's overall health, and mostly involve high cost and effort in manufacturing.

Considering the significance of increasing milk yield of cattle, there is a continuous requirement for medicines or compositions for milk yield enhancement, which would be economical, easily available and may have lower side effects and lower toxicities affecting a subject's body, which can be addressed by herbal compositions of the present invention.

OBJECT OF THE INVENTION:
The object of the invention is to provide novel herbal compositions which may be cost effective and easily available for increase and improvement of milk yield in a subject, and which have less or no side effects to the health of a subject.

SUMMARY OF THE INVENTION:
The present invention in a preferred embodiment provides herbal compositions for increase and improvement of milk yield in a subject, comprising of at least a part of Dioscorea bulbifera, to which parts of one or more additional complimentary herb may be optionally added, wherein the additional complimentary herb is also a herb for increase and improvement of milk yield in a subject and is selected from but not limited to Chenopodium ambrosioides seeds, Desmodium gangeticum leaves, Nigella sativa leaves, leaves, rice water, genera Centella, Withania, Asparagus, Chlorophytum, Boerhaavia, Sida, Saraca, Elettaria
cardamomum, Piper longum, Myristica fragrans fruit, or any combination thereof. The invention also provides for methods of preparation of the herbal compositions.

DETAIL DESCRIPTION OF THE INVENTION:
The present invention in a preferred embodiment provides herbal compositions for increase and improvement of milk yield in cattle, comprising of at least a part of Dioscorea bulbifera, to which parts of one or more additional complimentary herb may be optionally added, wherein the additional complimentary herb is also a herb for increase and improvement of milk yield in cattle and is selected from but not limited to Chenopodium ambrosioides seeds, Desmodium gangeticum leaves, Nigella sativa leaves, rice water, genera Centella, Withania, Asparagus, Chlorophytum, Boerhaavia, Sida, Saraca, Elettaria cardamomum, Piper longum, Myristica fragrans fruit, or any combination thereof.

Parts of Dioscorea bulbifera for the purpose of this invention includes the whole Dioscorea bulbifera, extract of Dioscorea bulbifera, pulverized form of Dioscorea bulbifera, crushed form of Dioscorea bulbifera, pieces cut or severed from Dioscorea bulbifera, chemical constituents of Dioscorea bulbifera along with their derivatives, or any combination thereof.

In an embodiment of the invention, the parts of Dioscorea bulbifera are severed by different methods such as but not limited to cutting, slicing, pounding, grinding, mashing or mincing.

The term 'herbal composition' for the purpose of this invention means a substance or mixture comprising of at least one natural component having medicinal property, wherein the natural component shall include a component extracted or derived from a natural source such as a herb or a shrub or a tree or a plant or parts thereof.

The term subject for the purpose of the invention means one or more of a human or any other animal which is capable of producing milk.

The herbs used for the compositions in accordance with the present invention, shall include other herbs of their respective species or family or genus which display similar medicinal properties.
In an embodiment of the invention, a solvent may be used for preparing the herbal compositions of the present invention, and the solvent used may be any suitable solvent such as but not limited to one or more of methanol, ethanol, n-propanol, isopropanol, hexane, heptane, petroleum ether, cyclohexane, diethyl ether, dusopropyl ether, ethyl acetate, methyl acetate, ethyl formate, methyl formate, isobutyl acetate, n-butyl acetate, methylene chloride, ethylene chloride, chloroform, carbon tetrachloride, acetone, ethyl methyl ketone, diisobutyl ketone, methyl isobutyl ketone, 1,4-dioxane, toluene, ammonia solution, glacial acetic acid, ammonium hydroxide, sodium hydroxide, calcium hydroxide, calcium carbonate, potassium hydroxide, water and other solvents known by those of skilled in the art.

In an embodiment of the invention, a suitable excipient is added to the herbal compositions of the present invention to prepare a consumable formulation for effective therapeutic delivery.

In an embodiment of the invention, the herbal compositions of the present invention may be formulated for oral administration by compounding the active ingredients with the usual nontoxic pharmacologically acceptable excipients for tablets, pellets, granules, capsules, solutions, emulsions, suspensions, and any other form suitable for use. Formulations in accordance with the present invention may include one or more of talc, water, glucose, lactose, gum acacia, gelatin, mannitol, starch paste, magnesium trisilicate, corn starch, keratin, colloidal silica, potato starch, urea, and other excipients suitable for use in manufacturing preparations, in solid, semisolid or liquid form, or any combination thereof. Additionally, auxiliary, stabilizing, thickening, flavoring, fragrance and coloring agents may be used.

In an embodiment of the invention, the herbal compositions can be administered in a solid form such as but not limited to tablets, capsules, pills, pellets, granules, boluses or powder. For preparing the solid form, the herbal compositions may be mixed with a pharmaceutical excipient such as but not limited to corn starch, lactose, sucrose, sorbitol, talc, stearic acid, magnesium stearate, dicalcium phosphate or gums, along with other pharmaceutical diluents. The solid compositions may be further subdivided into unit dosage forms containing an effective amount of compositions of the present invention.

In an embodiment of the invention, the herbal compositions can be administered in a liquid form such as but not limited to aqueous solution, suitably flavored syrups, aqueous
suspensions, oil suspensions, tinctures, tisanes, macerates and flavored emulsions with edible oils as well as elixirs or similar pharmaceutical carriers. The liquid form may include suitable dispersing or suspending agents for aqueous suspensions such as but not limited to tragacanth, acacia, alginate, dextran, sodium carboxymethyl cellulose, methylcellulose, polyvinylpyrrolidone or gelatin. Liquid preparations for oral administration may take the form of, for example, solutions, syrups or suspensions, or they may be presented as a dry product for reconstitution with water or other suitable vehicles before use.

In an embodiment of the invention, a process for preparing an herbal composition for increase and improvement of milk yield, comprise the steps of,

a) washing a part of *Dioscorea bulbifera*;
b) sieving the part of *Dioscorea bulbifera*; and
c) preparing pharmaceutically acceptable formulation thereof.

In an embodiment of the invention, a process for preparing an herbal composition for increase and improvement of milk yield, comprise the steps of,

a) washing a part of *Dioscorea bulbifera* and a part of an additional herb;
b) sieving the part of *Dioscorea bulbifera* and the part of the additional herb;
c) mixing the part of *Dioscorea bulbifera* and the part of the additional herb; and
d) preparing pharmaceutically acceptable formulation thereof.

In an embodiment of the invention, a process for preparing an herbal composition for increase and improvement of milk yield, comprise the steps of,

a) washing a part of root of *Dioscorea bulbifera* and a part of flower of *Desmodium gangeticum*;
b) sieving the part of *Dioscorea bulbifera* and the part of *Desmodium gangeticum*;
c) mixing the part of *Dioscorea bulbifera* and the part of *Desmodium gangeticum*; and
d) preparing pharmaceutically acceptable formulation thereof.

In an embodiment of the invention, a process for preparing an herbal composition for increase and improvement of milk yield, comprise the steps of,

a) washing a part of root of *Dioscorea bulbifera* and a part of flower of *Desmodium gangeticum*;
b) sieving the part of root of *Dioscorea bulbifera* and the part of flower of *Desmodium gangeticum*;
c) mixing 40 to 60% the part of root of *Dioscorea bulbifera* and 50 to 60% the part of flower of *Desmodium gangeticum*;
d) heating the above mixture in a vessel containing a solvent; and
e) preparing pharmaceutically acceptable formulation thereof.

In an embodiment of the invention, the herbal compositions may be delivered as a semi-solid form or gelatinous solid, such as but not limited to paste, jelly, gel or chutney.

In an embodiment of the invention, the herbal compositions may be delivered as a gaseous form or in form of aerosols which includes but not limited to spray, fumes, inhalers or mist.

In an embodiment of the invention, the herbal compositions may also be formulated for parenteral administration by injection, which includes but is not limited to, using conventional catheterization techniques or infusion.

In an embodiment of the invention, the herbal compositions may also be formulated for topical administration, in the form of solution, cream, gel, ointment, powder, paste, gum or lozenge, using techniques known to those skilled in the formulation field. As used herein, topical administration includes delivery of the compositions to mucosal tissue of the mouth, nose and throat by, for example, spray or mist application.

In an embodiment of the invention, the herbal compositions as an active ingredient may be used alone or in combination with other therapeutic agents, for increase and improvement of milk yield in a subject.

In an embodiment of the invention, the herbal compositions of the present invention may be in the form of a decoction or may be prepared using a decoction process.

In an embodiment of the invention, the parts of *Dioscorea bulbifera* can be given chemical treatment or made to react with other chemical reagents to form mixtures or herbal compositions which are used for increase and improvement of milk yield in a subject.
In an embodiment of the invention, the desirable dose of the compositions may vary depending on the condition and the weight of the subject, severity, drug form, route and period of administration.

It is observed that when more than one herb is used in the herbal compositions of the present invention, there is enhanced efficacy and the combination of herbs lead to synergistic effect.

The aim of this specification is to describe the invention without limiting the invention to any one embodiment or specific collection of features. A person skilled in the relevant art may realize the variations from the specific embodiments that will nonetheless fall within the scope of the invention, and such variations are deemed to be within the scope of the current invention.

It may be appreciated that various other modifications and changes may be made to the embodiment described without departing from the spirit and scope of the invention.
WE CLAIM:

1) Herbal compositions for increase and improvement of milk yield, the herbal compositions comprising at least a part of *Dioscorea bulbifera*.

2) Herbal compositions as claimed in claim 1, wherein said herbal compositions is selected from a group comprising whole *Dioscorea bulbifera*, extracts of *Dioscorea bulbifera*, crushed *Dioscorea bulbifera*, pulverized *Dioscorea bulbifera*, severed *Dioscorea bulbifera*, chemical constituents of *Dioscorea bulbifera*, and any combination thereof.

3) Herbal compositions as claimed in any of the preceding claims, wherein said herbal compositions further comprise additional herbs.

4) Herbal compositions as claimed in any of the preceding claims, wherein所述 herbal compositions further comprise additional herbs selected from *Chenopodium ambrosioides* seeds, *Desmodium gangeticum* leaves, *Nigella sativa* leaves, rice water, genera *Centella*, *Withania*, *Asparagus*, *Chlorophytum*, *Boerhaavia*, *Sida*, *Saraca*, *Elettaria cardamomum*, *Piper longum*, *Myristica fragrans* fruit, and any combination thereof.

5) Herbal compositions as claimed in any of the preceding claims, wherein the herbal compositions of the invention further comprises one or more of solvents, excipients, auxiliary agents, stabilizing agents, thickening agents, flavoring agents, fragrance, preservatives, fillers, coloring agents, and any combination thereof.

6) Herbal compositions as claimed in any of the preceding claims, wherein the herbal compositions is in forms selected from a group comprising of injectable forms; solid tablets, pellets, granules, capsules, forms; oral usage form; topical application form; semi-solid form; gaseous form; and any combination thereof.

7) A process for preparing an herbal composition for increase and improvement of milk yield, comprise the steps of,

   a) washing a part of *Dioscorea bulbifera*;
   b) sieving the part of *Dioscorea bulbifera*; and
c) preparing pharmaceutically acceptable formulation thereof.

8) A process for preparing an herbal composition as claimed in any of the preceding claims, comprise the steps of,
   a) washing a part of *Dioscorea bulbifera* and a part of an additional herb;
   b) sieving the part of *Dioscorea bulbifera* and the part of the additional herb;
   c) mixing the part of *Dioscorea bulbifera* and the part of the additional herb; and
   d) preparing pharmaceutically acceptable formulation thereof.

9) A process for preparing an herbal composition as claimed in any of the preceding claims, comprise the steps of,
   a) washing a part of *Dioscorea bulbifera* and a part of *Desmodium gangeticum*;
   b) sieving the part of *Dioscorea bulbifera* and the part of *Desmodium gangeticum*;
   c) mixing the part of *Dioscorea bulbifera* and the part of *Desmodium gangeticum*;
      and preparing pharmaceutically acceptable formulation thereof.

10) A process for preparing an herbal composition as claimed in any of the preceding claims, comprise the steps of,
    a) washing a part of root of *Dioscorea bulbifera* and a part of flower of *Desmodium gangeticum*;
    b) sieving the part of root of *Dioscorea bulbifera* and the part of flower of *Desmodium gangeticum*;
    c) mixing 40 to 60% the part of root of *Dioscorea bulbifera* and 50 to 60% the part of flower of *Desmodium gangeticum*;
    d) heating the above mixture in a vessel containing a solvent; and
    e) preparing pharmaceutically acceptable formulation thereof.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

INV. A23K1/18 A61K36/8945 A61K36/48

ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

INV.

A61K36/8945 A61K36/48

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A23K A61K

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)

EPO-Internal, BIOSIS, FSTA, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>DATABASE TKDL [Online]</td>
<td>1-4,6</td>
</tr>
<tr>
<td></td>
<td>1979, ANONYMUS: &quot;ASTAVARGA GUNA&quot;, XP002678320, Database access on no. RS15/44</td>
<td></td>
</tr>
<tr>
<td>Y</td>
<td>the whole document</td>
<td>5,7-10</td>
</tr>
<tr>
<td>X</td>
<td>DATABASE TKDL [Online]</td>
<td>1-3,6</td>
</tr>
<tr>
<td></td>
<td>1998, ANONYMUS: &quot;ALUKA GUNA&quot;, XP002678319, Database access on no. RS15/576</td>
<td></td>
</tr>
<tr>
<td>Y</td>
<td>the whole document</td>
<td>5,7-10</td>
</tr>
</tbody>
</table>

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 application of patent but published on or after the international filing date

*L* document which may throw doubts on priority claim(s) on which it is cited to establish the publication date of another citation or other special reason (as specified)

*O* document referring to an oral disclosure, use, exhibition or other means

*P* document published prior to the international filing date but later than the priority date claimed

*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

*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

*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

*"* document member of the same patent family

Date of the actual completion of the international search: 22 June 2012

Date of mailing of the international search report: 05/07/2012

Name and mailing address of the ISA:
European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer
Munteanu, Ioana S.
### DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
</table>
| A        | DATABASE TKDL [Online]  
1986,  
ANONYMUS: "BRHAT CHAGALADI GHRTA",  
XP002678318,  
The whole document  
-----  | 4, 9, 10  |
| Y        | JP 8 325159 A (AKAHA TORU)  
10 December 1996 (1996-12-10)  
Paragraph [0005] - Paragraph [0012]  
-----  | 5, 7-10  |
<table>
<thead>
<tr>
<th>Patent document cited in search report</th>
<th>Publication date</th>
<th>Patent family member(s)</th>
<th>Publication date</th>
</tr>
</thead>
</table>