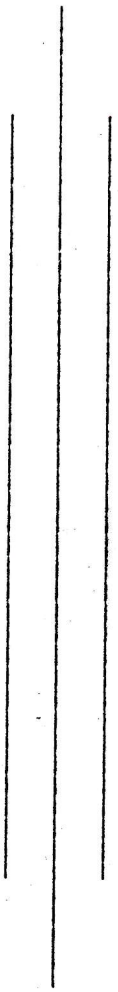
CDC: Nepal

Breastmilk Substitutes (Marketing Control) Regulation, 2051(1994)



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Breastmilk Substitutes (Marketing Control) Regulation, 2051 (1994)

In exercise of the power conferred by Section 20 of the Breastmilk Substitutes (Marketing Control) Act, 2049 (1992) His Majesty's Government has made the following Rules.

1. Short Title and Commencement :

(1) These Rules may be called the Breastmilk Substitutes (Marketing Control) Regulation, 2051 (1994).

(2) It shall come into force immediately.

2. Definitions :

Unless the subject or context otherwise requires, in this Regulation,-

(a) "Act" means the Breastmilk Substitutes (Marketing Control) Act, 2049 (1992).

(b) "Inspector" means the person appointed or designated as Inspector under sub - section (1) of Section 13 of the Act.

3. Monitoring :

For the promotion and protection of breastfeeding the Committee may itself or through sub-committee or Inspectors monitor the compliance of the provisions of the Act and this Regulation by the health workers, health care facilities and the manufacturers or distributors of the infant foods including breastmilk substitutes.

4. Application for Approval :

(1) In case the health care facility or any other institution or organization wants to take any product at lower than retail price or as donation from any manufacturer or distributor pursuant to sub-section (7) of Section 9 of the Act it shall submit an application stating the objects and reasons thereof in the form of Schedule -1 to the Committee for its approval.

7. Approval for Label :

(1) Manufacturers or distributors shall submit the label of the products to the Committee for approval before the products may be sold with an application in the form of Schedule - 5.

(2) In case any application is submitted pursuant to sub-rule (1) the Committee shall, if it finds that the concerned label contains all the matters required to be mentioned under sub- section (6) of Section 11 of the Act, approve such label within thirty days from the date of submission of such application.

8. Records to be Maintained :

The Committee shall maintain the records of all matters for which it has given approval pursuant to Rule 5 or 7.

9. Delegation of Powers :

The Committee may delegate the powers, conferred upon it by the Act and this Regulation, to the sub-committee constituted under clause of Section 6 of the Act, the member secretary of the Committee or any other employee.

10. Identity Card :

(1) An identity card in the form of Schedule - 6 shall be given to the Inspectors.

(2) The Inspector shall always hold its identity card and in case any body demands to see his identity card while he is carrying out any function or exercising the powers conferred by the Act and this Regulation he shall show it immediately.

11. Inspection :

(1) The Inspector shall inspect the maternity home, maternity and paediatric wards of hospitals; health care centers, offices or clinics of the health professionals, offices of other health care facilities and health workers and production unit or godown or offices of the manufacturer or distributor within his jurisdiction at least two times in a year and make enquiry about the compliance of the provisions of the Act and this Regulation by them.

(2) The Inspector may enter into the land and building of any person by giving notice to the concerned person in accordance with the prevailing law if it requires to do so for the purpose of making inspection and enquiry pursuant to sub-rule (1).

(3) In case the Inspector requires the help for the purpose of making inspection and enquiry pursuant to sub-rule (1) and (2) the local body, administration, police and the concerned person shall provide assistance to him.

12. Directives may be Given :

(1) In case the Inspector finds any irregularities, while making inspection and enquiry pursuant to Rule 11, in any maternity home, maternity and paediatric ward of the hospital, health care center, office or clinic of the health professionals or any other health care facility he may issue necessary directives to correct such irregularities or to improve the services to be provided therein.

(2) The Chief of the concerned maternity home, hospital, health care center, health care facility and health professionals shall comply with the directives given by the Inspector pursuant to sub-rule (1).

13. Report to be submitted :

The Inspector shall, after making inspection and enquiry pursuant to Rule 11, prepare an inspection report stating his suggestion and the directives he has given under Rule 12 in addition to the matters he has observed and submit it to the Committee.

14. Changes in Schedules :

His Majesty's Government may, be a notification published in the Nepal Gazette, make necessary changes in the Schedules.

Schedule - 1
(Relating to sub-rule (1) of Rule 4)

Date :.....

The Committee for the Promotion and Protection of Breastfeeding
.....

Sir,

I / We hereby submit this application for your approval to take the following products at lower price than retail price or as donation from the following manufacturer or distributor.

(a) Name of the manufacturer or distributor :-

(b) Address :-

(c) Name of the product :-

(d) Quantity :-

(e) Cost :-

Applicant's,-

Signature :-

Name :-

Designation :-

Schedule - 2
(Relating to sub-rule (2) of Rule (4)

Date: .....

The Committee for the Promotion and Protection of Breastfeeding
.....

Sir,

I/we hereby submit this application for the approval of the Committee to donate the following equipments or materials to the following health care facility.

(a) Name of the health care facility :-

(b) Address :-

(c) Details of the equipment or material :-

(d) Quantity :-

(e) Cost :-

(f) Name of the manufacturer or distributor :-

(g) Address :-

(h) Main objects and reasons for donation:-

Applicant's,-

Signature :-

Name :-

Designation:-

Schedule - 3
(Relating to sub-rule (3) of Rule 4)

Date:

The Committee for the Promotion and Protection of Breastfeeding
.....

Sir,

I/we hereby submit this application for the approval of the Committee to take fellowship, research grant or fund for sponsoring or attending the professional meeting or conference from the following manufacturer or distributor.

(a) Name of the manufacturer or distributor :-

(b) Address :-

(c) Details of the fellowship or research:-

(d) Required fund for the fellowship or research :-

(e) Details of the professional meeting or conference :-

(f) Venue of the meeting or conference :-

(g) Date and period of the meeting or conference :-

(h) Required fund for sponsoring or attending the meeting or conference :-

(i) Details of the qualification of the applicant :-

(j) Address :-

Applicant's,-
Signature :-
Name :-

Schedule - 4
(Relating to sub-rule (1) of Rule 6)

Date:.....

The Central Food Laboratory,
.....

Sir,

I/wehereby submit this application along with the sample of the product and necessary fee for the certification of the following products.

(a) Name of the manufacturer or distributor :-

(b) Address :-

(c) Name of the products :-

(d) Ingredients of the products :-

(e) Composition and analysis of the products :-

(f) Label of the product is approved or not :-

(g) If approved the date of such approval :-

Applicant's

Signature :-

Name :-

Designation :-

Schedule - 6
(Relating to sub-rule (1) of Rule 10)

His Majesty's Government
Ministry of Health

.....

Inspector's,

Name :-

Signature :-

Jurisdiction :-..... District

Identity Card issuing officer's,-

Name :-

Signature :-

Designation :-

Identity Card No.:

Date :-

Photo of the Inspector

Seal of the office.....(touching the Photo)