(Legislative Supplement No. 72)

LEGAL NOTICE NO. 184

THE BREAST MILK SUBSTITUTES (REGULATION AND CONTROL) ACT

(No. 34 *of* 2012*)*

THE BREAST MILK SUBSTITUTES (REGULATION AND CONTROL) (GENERAL) REGULATIONS, 2021

ARRANGEMENT OF REGULATIONS

Regulation

THE BREAST MILK SUBSTITUTES (REGULATION AND CONTROL) ACT

(No. 34 of 2012)

IN EXERCISE of the powers conferred by section 28 of the Breast Milk Substitutes (Regulation and Control) Act, 2012, the Cabinet Secretary responsible for matters relating to public health, makes the following Regulations—

THE BREAST MILK SUBSTITUTES (REGULATION AND CONTROL) (GENERAL) REGULATIONS, 2021

Citation.

1. These Regulations may be cited as the Breast Milk Substitutes (General) Regulations, 2021.

Interpretation.

2. In these Regulations, unless the context otherwise requires—

"Act" means the Breast Milk Substitutes (Regulation and Control) Act;

"cross-promotion" means a form of marketing promotion where customers of one product or service are targeted with the promotion of a related product using symbols, colouring, naming, shelf placement or any other means that implies benefit or suitability;

"donation" means a designated product or pre-packaged complementary food offered for charity or humanitarian aid;

"donee" means the person or institution receiving the donation;

"donor" means the person or institution making the donation;

"KS CODEX STAN" means any Codex Standard that has been approved as the Kenya standards under the Standards Act;

"KS EAS" means an East African Standard that has been approved as a Kenya standard under the Standards Act;

"KS" means a Kenya Standard approved under the Standards Act; and

"public analyst" means a health officer who examines, reviews, evaluates, or conducts research of designated products and pre-packaged complementary food.

Guiding principles.

3. (1) The guiding principles for interpreting the Act and these Regulations, binds the authorised officers and all persons whenever any of them—

(a) applies or interprets any provision of these Regulations;

(b) are involved in the manufacture, distribution, study, or advising about the use of designated products or complementary foods or about breastfeeding; and

(c) makes or implements public policy decisions.

(2) Without prejudice to the generality of sub-regulation (1), an authorised officer shall in the discharge of his or her functions under these Regulations, ensure that—

(a) in the provision of nutrition services, the best interest of an infant and young child is protected;

(b) initiation of breastfeeding of the infant is done within an hour of delivery and exclusive breastfeeding for the first six (6) months of life;

(c) timely introduction of appropriate, adequate and safe complementary food with continued breastfeeding for a period of twenty-four (24) months or beyond;

(d) where appropriate, breastmilk substitutes and pre-packaged complementary food shall be safe for the consumption of an infant and young child;

(e) adequate and accurate information on breastfeeding and infant and young child feeding shall be available to the general public; and

(f) interaction with manufacturers and distributors of designated products shall be done in the manner prescribed under the Act and these Regulations.

Objects.

4. The objects of these Regulations is to guide all persons that use, manufacture, sell and market breast milk substitutes and to ensure that all persons understand that breast milk substitutes undermines breastfeeding and suboptimal breastfeeding is a leading but preventable cause of death and serious illness in infants and young children.

PART II—PROCEDURES RELATING TO THE USE OF DESIGNATED PRODUCTS AND PRE-PACKAGED COMPLEMENTARY FOOD.

Production and packaging of designated and complementary food products.

5. The production, preparation and packaging of designated products and pre-packaged complementary food shall be in accordance with—

(a) the provisions of the Act, the Food, Drugs and Chemical Substances Act, the Public Health Act, the Standards Act and the Kenya Standards KSEAS 39 and any other written law; and

Cap. 254, *Cap.*242 and *Cap.* 496.

(b) the Kenya standards for infant formula (KS EAS4), follow up formula (KS CODEX STAN 156), formulated pre-packaged complementary food for older infants and young children (KS-2515) and processed cereal based foods for infants and young children (KS EAS 72).

Registration.

6. Every manufacturer or importer of designated products shall register with the office in charge of nutrition and dietetics in the Ministry responsible for matters relating to public health, by providing its physical address, telephone, website, and email contact information and declaring that the products it imports or distributes are subject to this Act and shall provide updated information within 30 days of these declared information changing.

Sampling and testing.

7. Sampling and testing of the designated products and pre-packaged complementary food shall be in accordance with the provisions of the Act, the Food, Drugs and Chemical Substances Act, the Public Health Act and the Standards Act and any other written law.

Complying with Regulations.

8. A manufacturer, trader, importer and distributor shall not import, offer for sale or sell any designated product or pre-packaged complementary food if it does not comply with these Regulations, the Act and any other relevant written law.

Manufacturing, sell and expiry date.

9. No person shall stock, distribute, sell or exhibit any food for infant and young child which does not have a manufacturing date and an expiry date.

Use of alternative containers from the original.

10. Any person who stocks, distributes, sells or exhibits a designated product or pre-packaged complementary food for use by infants or young children in an alternative container from the original containers shall hermetically seal and label the alternative container in accordance to the Act and any other written law.

Certificate of analysis.

11. (1) An authorised officer may at any time, collect and submit to a public analyst a sample of a designated product or a pre-packaged complementary food product for analysis.

(2) The public analyst referred to under sub-regulation (1), shall upon analysis of the product, issue a certificate of analysis.

PART III—DONATIONS OF DESIGNATED PRODUCTS AND PRE-PACKAGED COMPLEMENTARY FOOD

Application to donate.

12. (1) A person or institution who undertakes to make a donation of a designated product or pre-packaged complementary food product to a charitable children institution or social welfare institution under the Act or these Regulations shall make an application, in writing, to the Committee for approval.

(2) An application made under sub-regulation (1), shall be accompanied by a duly completed Form BMS 1 in the Schedule to these Regulations.

Restrictions to donations.

13. (1) A person making a donation under the Act or these Regulations shall not advertise or publicize the making of such donation.

(2) The product being donated under sub-regulation (1), shall meet all the requirements of both the Kenyan and applicable international standard as prescribed in law and have at least fifty percent (50%) shelf life before expiry.

(3) The product being donated under sub-regulation (1), shall be in the original container with a clear label marked "Not for Sale".

(4) Donations of designated or pre-packaged complementary food products to charitable children institutions or social welfare institution, made under the Act and these Regulations shall be for the purpose for which they were donated.

(5) Without prejudice to the generality of sub-regulation (3),

donations made to a charitable children institution or social welfare institution shall be used within the institution to which they are donated and shall not be distributed outside that institution unless further donated to another charitable children or social welfare institution with prior written consent of the Committee.

Filing of returns.

14. (1) A person or institution making a donation under the Act and these Regulations shall within two weeks of making such donations, file returns with the Committee and the Director of Children Services, in Form BMS 2 in the Schedule to these Regulations.

(2) A donee upon receipt of the donations under the Act and these Regulations, shall within two weeks, file returns for use to the Committee in Form BMS 3 in the Schedule to these Regulations.

(3) A donee shall upon utilization of the donations under sub Regulation (1), file returns with the Committee in Form BMS 4 in Schedule to these Regulations indicating details of the number of children benefiting from the donations and the health outcomes of those recipients.

Application by charitable and social institutions.

15. A person of institution that wishes to apply for donation of a designated product or a pre-packaged complementary food product shall apply in writing to the committee for directions.

Use of donations.

16. (1) Donations of a designated product or a pre-packaged complementary food product shall be used only for purposes of benefiting infant and young children to optimal health outcomes of all recipients.

(2) No person shall, for the purpose of donating any designated product or a pre-packaged complementary food product, without the written approval of the Committee, directly donate or give to any person, institution or health facility any designated product or a pre-packaged complementary food product thereof.

PART IV—LABELLING OF DESIGNATED PRODUCTS AND PRE-PACKAGED COMPLEMENTARY FOOD

Labelling of designated products and pre-packaged complementary food product.

17. (1) The label of a designated product or complementary food product, shall in addition to the provisions of the relevant written legislation or Kenya standard, contain the name, physical address, website address, email address and telephone number of the manufacturer, seller and, if imported to Kenya, contact information of the responsible importer.

(2) Not withstanding sub-regulation (1), the label of a designated product or pre-packaged complementary food shall not refer to, promote or advertise any other designated product.

Prohibitions on labelling

18. A label or a container of a designated product or a pre-packaged complementary food shall not contain a photograph, drawing or other graphic representation other than for illustrating how the product is to be used.

Labelling of infant formula and follow-up formula.

19. (1) A person shall not offer for sale or sell infant formula and follow-up formula unless the container and the label affixed thereto,

contains the following words expressed in English or Kiswahili language in bold and conspicuous characters in a prominent position and in not less than fifty percent (50%) of the size of the largest words on the label in red lettering on white background and not less than 3 mm in height based on the lower case "o" preceded by the word "WARNING" in capital letters:

"'Breast milk is best. Breast milk is ideal for the healthy growth and development of infants and young children. It protects against potentially fatal diarrhea, lung infections and other illness. It is often difficult to resume breastfeeding after beginning to feed your baby breast milk substitutes."

(2) The label on any container of infant formula shall—

(a) not include words such as "maternalised" or "humanised" or images, symbols or words that glorify or otherwise imply that feeding infants breast milk substitutes is natural or promotes cognitive, growth or other developmental goals;

(b) not contain any text, graphics or pictures that may tend to discourage breastfeeding;

(c) specify the source of protein; and

(d) in case of follow up formula, state that the product shall not be used for infants who are less than six months old.

Containers of designated and pre-packaged complementary food.

20. A label affixed to a container containing a designated product or pre-packaged complementary food, shall indicate in a clear, conspicuous and easily readable manner in English or Kiswahili language and easily understood graphics indicating—

(a) instructions for appropriate preparation and use;

(b) the age range for which the product is recommended for use in numeric figures, in the case of complementary food, shall not be younger than six months;

(c) a warning about the health risks of improper preparation and of using the product before the recommended age; and

(d) such other particulars as may be subsequently provided from time to time by the Committee.

Labelling of formula in powdered form.

21. Despite any other requirement in these Regulations with respect to containers or labels of infant formula or follow up formula, labelling for infant or follow up formula in powdered form shall, in addition to including a feeding chart, indicate that—

(a) powdered formula may be contaminated during the manufacturing process or may become contaminated during preparation;

(b) it is necessary for formula to be prepared one feed at a time using clean and safe water that has been boiled and cooled within 30 minutes;

(c) any unused milk shall be discarded immediately after every feed.

Labelling requirements for feeding bottles.

22. A label, package or a container of a feeding bottle and the bottle itself shall indicate in a clear, conspicuous and easily readable manner in English or Kiswahili language the following words in not less than 50% of the size of the largest words on the label not less than 3 mm in height based on the lower case "o" preceded by the word "WARNING" in capital letters:

"Breastfeeding is best. Breastfeeding is ideal for the healthy growth and development of infants and young children. It protects against potentially fatal diarrhea, lung infections, and other illness".

Labelling requirements for teats.

23. (1) A label on a package or container of a teat shall not—

(a) show any graphic representation other than for illustrating cleaning, the logo of manufacturer or distributer;

(b) contain words or images idealizing the use of teats; and

(c) compare the act of suckling the teat to the action, motion or benefits of suckling human breast or physical properties of such human breast.

(2) A label, package or a container of a pacifier and the surface of the pacifier itself shall indicate in a clear, conspicuous and easily readable manner in English or Kiswahili language the following words in not less than 50% of the size of the largest words on the label not less than 3 mm in height preceded by the word "WARNING" in capital letters:

"Use of teats can interfere with breastfeeding."

Labelling requirements for pacifiers.

24. (1) A label on a package or container of a pacifier shall not—

(a) show any graphic representation other than for illustrating cleaning, the logo of manufacturer or distributer;

(b) contain words or images idealizing the use of teats;

(c) compare the act of suckling the teat to the action, motion or benefits of suckling human breast or physical properties of such human breast.

(2) A label, package or a container of a pacifier and the surface of the pacifier itself shall indicate in a clear, conspicuous and easily readable manner in English or Kiswahili language the following words in not less than 50% of the size of the largest words on the label not less than 3 mm based in height based on the lower case "o" in red lettering on white background preceded by the word "WARNING" in capital letter:

"Use of pacifier can interfere with breastfeeding".

Particulars to be inscribed on container.

25. (1) No person shall sell, display for sale, consign or deliver any designated product or a pre-packaged complementary food product in a container, unless the container bears a label on which there appears—

(a) in English or Kiswahili language, a true statement of the product as to the following matters—

(i) ingredients;

(ii) required storage condition;

(iii) date of manufacture;

(iv) batch number; and

(v) expiry date.

(b) on a label marked on or securely attached to the container the following statement in red bold text against a white background;

"WARNING": Breastfeeding is best. Breastfeeding is ideal for the healthy growth and development of infants and young children. It protects against potentially fatal diarrhea, lung infections, and other illness".

(2) Any label affixed to any container of a designated product or a pre-packaged complementary food product as required under sub-regulation (1), shall bear directions for use in English or Kiswahili language and such adequate warnings against the health hazards of inappropriate preparation or use.

(3) The statement referred to in sub-regulation (1) shall—

(a) be clearly legible and shall appear conspicuously and in a permanent position on the label;

(b) specify the name of either the manufacturer, distributor, packer or labeler of the breast milk substitute or infant formula; and

(c) bear a physical address, website address, telephone number, and email address at which such person carries on business which shall be clearly shown in all notices, advertisements and other publications used by such person in connection with his business as dealer in the designated product or a pre-packaged complementary food product.

PART V—INTERACTIONS BETWEEN MANUFACTURERS, DISTRIBUTORS AND HEALTH WORKERS.

Interactions.

26. (1) Any interactions between a manufacturer or distributor with any health worker shall strictly be limited—

(a) to creating awareness about scientific and factual matters on designated products and pre-packaged complementary food;

(b) to providing samples of designated products and pre-packaged complementary food for professional evaluation; and

(c) to providing samples of designated products and complementary foods for research on the product.

(2) The interactions between a manufacturer or distributor with any health worker referred to under sub-regulation (1), shall take place

in a public venue approved by the Committee pursuant to a decision-making process consistent with the Fair Administrative Action Act, 2015. No. 4 of 2015.

Creating awareness.

27. (1) Subject to section 6(3) of the Act, a manufacturer or distributor who wishes to create awareness about the scientific and factual matters of the breast milk substitute or complementary food product, shall before commencing interactions with any health worker apply in writing to the Committee for approval.

(2) An application made under sub-regulation (1), shall expressly provide for the following information—

(a) a sworn statement that the interaction does not imply an endorsement of the designated product or pre-packaged complementary food;

(b) a sworn statement that there is no existing relationship, collaboration or partnership or intended relationship, collaboration or partnership with the health worker;

(c) particulars of the health workers targeted for awareness;

(d) proposed public venue;

(e) sample of the designated product or pre-packaged complementary food to be used during the interaction;

(f) a certificate of analysis from a public analyst in Kenya;

(g) a detailed report on scientific findings and evidence based research on the benefits of the product;

(h) a peer-reviewed scientific information of the product;

(i) proof that the designated product or pre-packaged complementary food to be used during the interaction meets the national and international standards; and

(j) any other relevant document requested by the Committee.

(3) An applicant who is required to supply additional information under paragraph (j), shall do so within a period of 30 days from the date of the request.

Professional evaluation.

28. (1) Any interactions between a manufacturer or distributor and a health worker for the purposes of professional evaluation of a designated product or pre-packaged complementary food shall commence only after approval by the Committee.

(2) Any health worker participating in the interaction under sub-regulation (1), shall—

(a) before commencing the interaction, seek written approval from the Committee; and

(b) state in writing that the interaction does not imply an endorsement of the designated product or pre-packaged complementary food and that there is no existing relationship, collaboration or partnership or intended

relationship, collaboration or partnership with the manufacturer or distributor.

(3) The application referred to under sub-regulation (1) shall be accompanied by—

(a) an approved research protocol;

(b) an ethics approval from a competent and recognised authority responsible for research and innovation in Kenya issued pursuant to the Science, Technology and Innovation Act, 2013;

(c) a certificate of analysis; No. 28 of 2013.

(d) proof of use in country of origin if the product is not made in Kenya;

(e) ethics approval from a competent authority if the product is originating outside of Kenya; and

(f) any other document the Committee may require.

Formal record.

29. Any health worker who wishes to participate in any interaction with a manufacturer or distributor, for the purposes of professional evaluation, or research on a designated product or pre-packaged complementary food, shall prepare a formal record of the interaction and submit it to the Committee, within 30 days following the interaction.

Restrictions to interactions.

30. (1) A manufacturer or distributor during the interaction with a health worker shall not—

(a) distribute any promotional material or items;

(b) give misleading information prohibited under the Act;

(c) engage in activities that are not approved by the Committee;

(d) distribute any samples of designated or pre-packaged complementary food product;

(e) hold the event at an alternative venue not approved; and

(f) brand the venue in any way to promote a designated or packaged complementary food.

Cross-promotion.

31. A manufacturer or distributor of a designated product or a pre-packaged complementary food shall not engage in cross-promotion.

Advertisement.

32. A person who makes a representation either directly or indirectly with an intention of promoting the sale or use of designated or pre-packaged complementary food product, either through—

(a) written publication, television or radio broadcast, film or electronic transmission, including the Internet, video or telephone;

(b) displays, signs, symbols, colours, billboards or notices; or

(c) exhibition of pictures or models,

commits an offence.

Demonstration for use of a pre-packaged complementary food product.

33. The method used by a health worker during demonstrations for use of complementary food product shall be either one-on-one or in a group and shall contain the following information—

(a) the benefits and superiority of breastfeeding;

(b) the value of exclusive breastfeeding for the first six months followed by sustained breastfeeding for up to 2 years or beyond;

(c) the proper preparation and use of the product;

(d) that use of cup or spoon feeding is safer than bottle or spout feeding;

(e) the importance of feeding infants with an open cup and spoon; and

(f) how complementary food can easily be prepared at home using local ingredients.

Procedure for demonstration for use of infant and follow-up formula.

34. (1) The method used by a health worker during demonstrations for use of infant formula and follow-up formula shall be one-on-one in a secluded area and shall—

(a) be in the original container of manufacture;

(b) maintain hygiene;

(c) follow the manufacturer's instruction for preparation;

(d) issue the supplies in a plain packaging that conceals the brand name;

(e) declare whether the health facility is baby friendly; and

(f) make available the most recent document on demonstrations and their source.

(2) A health worker while conducting a demonstration under sub-regulation (1), shall inform the infant's mother on—

(a) the benefits and superiority of breastfeeding;

(b) how to initiate and sustain breastfeeding;

(c) the importance of periodic HIV/AIDS testing of parents, adherence to maternal Anti-Retroviral treatment and infant prophylaxis, early infant diagnosis, continued Anti-Retroviral treatment, and continued breastfeeding by mothers who are infected with HIV/AIDS;

(d) the value of exclusive breastfeeding for the first six month of life and continued breastfeeding with introduction of nutritionally adequate and safe complementary foods for up to 2 years or beyond;

(e) the importance of optimal maternal nutrition;

(f) the difficulty of returning to breastfeeding after a period of artificial feeding;

(g) the approximate financial cost of adequate feeding of an infant with breastmilk substitutes during the first six months of life;

(h) why it is difficult to return to breastfeeding after starting to feed babies on breastmilk substitutes;

(i) the importance of not introducing complementary foods until after six months of life;

(j) the negative effects of artificial feeding on lactation and how early introduction of complementary food interferes with breastfeeding;

(k) instructions on proper preparation and use of the product;

(l) the potential health hazards of feeding bottles and cups with spouts;

(m) the importance of feeding an infant with an open cup and spoon; and

(n) how to feed an infant with an open cup and spoon.

Procedure for demonstrating proper complementary feeding.

35. (1) The method used by a health worker during demonstrations for complementary feeding for infants and young children aged 6-36 months—

(a) shall conceal brand name of the product;

(b) shall maintain hygiene; and

(c) follow the manufacturer's instruction for preparation.

(2) A health worker while conducting a demonstration under sub-regulation (1), shall inform the infant's mother on—

(a) the value of exclusive breastfeeding for the first six months of life and continued breastfeeding with introduction of nutritionally adequate and safe complementary foods for up to two years or beyond;

(b) the importance of optimal maternal nutrition;

(c) the negative effects of artificial feeding on lactation and how mixed feeding interferes with breastfeeding;

(d) instructions on proper preparation and use of the product that emphasize home-prepared, use of locally available foods, suitability of the foods, nutrient-density, safe preparation, and safe feeding.

PART VI—INFORMATION, EDUCATION AND COMMUNICATION MATERIALS

Publication of information, education and communication materials.

36. (1) Notwithstanding any other provision of these Regulations, no person shall publish or cause or permit to be published or distributed any informational or educational or communication material that relates to infant and young children feeding unless approved by the Committee.

(2) For the purposes of approval under sub-regulation (1), a person shall submit an application letter, together with a sample of the proposed material to be published or distributed containing any informational or educational or communication material that relates to infant and young children feeding.

(3) The Committee shall respond, in writing, to the application made under sub-regulation (1) within twenty-one days of the receipt of the application, and may approve upon satisfaction that the information, education and communication materials comply with the provisions of regulation 37 of these Regulations.

Contents of information, education and communication materials.

37. The contents of the information, education and communication materials under these Regulations shall—

(a) be written in easily readable and understandable English or Kiswahili;

(b) not make reference to any brand name or logo of any breast milk substitutes;

(c) substitute, pre-packaged complementary food or designated product;

(d) not give an impression or create a belief that a designated product is equivalent to, comparable with or superior to breast milk or to breastfeeding;

(e) not include a brand name, logo or name of the manufacturer or distributor of designated products or pre-packaged complementary food;

(f) include only factual, scientific and current information and is not presented in any picture that encourages bottle feeding or discourages breastfeeding;

(g) comply with the provisions of the Act and these Regulations;

(h) not include a photograph of an infant; and

(i) not include words or images that create the impression that the use of designated products are manufactured in accordance with the recommendation of a health professional registered under any of the health professional regulatory bodies in Kenya.

PART VII—ENFORCEMENT

Authorised persons.

38. An authorised officer may, in addition to the provisions of section 11 of the Act, include a health worker, custom officer, police officer or officers from the body responsible for Standards.

Access to breast milk substitutes.

39. A manufacturer or distributor, upon request, shall produce any prescribed designated product or pre-packaged complementary food to an authorised officer.

Seizures.

40. (1) Where an authorised officer finds any designated product or pre-packaged complementary food at any premises and the officer is satisfied, on reasonable grounds, that the goods are—

(a) prohibited goods; or

(b) not being sold by an authorised manufacturer, wholesaler, distributor or retailer of goods,

the officer may, without laying any information or obtaining any warrant, seize and remove those goods.

(2) Seizure of goods under these Regulations and Act by an authorized officer shall be in accordance to Form A and B provided for in the Schedule to these Regulations.

Conflict of Interest.

41. (1) A health worker who has any pecuniary or business interest, in any designated product or pre-packaged complementary food shall disclose the nature of the interest to the Committee, on commencement of employment and as soon as the relevant facts have come to his or her knowledge.

(2) A disclosure of interest under sub-regulation (1), shall be recorded by the Committee.

(3) A health worker having made such a disclosure shall not be present during any interactions under the Act.

General penalty.

42. A person who contravenes any of the provisions of these Regulations, shall be liable on to conviction, in accordance to the Act.

Spot fines.

43. A person who without lawful excuse the proof of which shall lie with him or her breaches any of these Regulations shall be liable, upon an inspection, by an inspector who attests to an honest belief and the balance of probability that such breach has been committed of an administrative monetary penalty of no more than 20,000 Kenya Shillings.

Subsequent offences.

44. If a person is found to breach any provisions of these Regulations two or more times, the Cabinet Secretary responsible for public health may issue an order for a penalty to be issued in relation to each violation of the Regulations in respect of each unit sold in the case of labelling or distribution offenses or each person estimated to have been reached by advertising or promotional campaigns.

Review.

45. The Cabinet Secretary may from time to time review these Regulations for the better implementation of the Act.

SCHEDULE

(r. 12(2))

Form BMS 1

APPLICATION FOR DONATION

Donation Case No:.....Date:.....

TAKE NOTICE that I/We.....(Name of donor) of Identity/Registration No.:..... and Address.....seek consent to be allowed to make a donation to.....(Name of donee)

DESCRIPTION OF THE DONOR

Name: .....

Address:.....

Telephone:.....

Email: .....

Type of institution:.....

Date of incorporation:.....

Reason for donation:.....

.....

DESCRIPTION OF THE DONEE

Name: .....

Address.....

Telephone:..... Email:.....

Types of institution:.....

Date of incorporation:.....

DESCRIPTION OF THE DONATION

Name:.....

Name of the manufacturer/dealer:.....

Manufacturer date: .....

Batch No.:.....

Expiry date: .....

Quantity donated: .....

Donor/Donee

Name: ..... Name:.....

Signature:..... Signature:.....

Date:..... Date:.....

FORM BMS 2

(r. 14(1))

RETURNS FOR DONATION

Donate Case No:.....Date:.....

TAKE NOTICE that I/We.....(Name of donee) of Identity/Registration No.:.....and Address.....seek to make returns of products donated to us on the.....day of.....by.....(Name of donor).

DESCRIPTION OF THE DONOR

Name: .....

Address:.....

Telephone:.....

Email: .....

Type of institution: .....

Date of incorporation: .....

Reason for donation: .....

.....

DESCRIPTION OF THE DONEE

Name: .....

Address.....

Telephone:.....

Email: .....

Types of institution: .....

Date of incorporation: .....

DESCRIPTION OF THE DONATION

Name: .....

Name of the manufacturer/dealer:.....

Manufacturer date:.....Batch No.:.....

Expiry date:.....

Quantity donated:.....

Donee/Donor

Name: ..... Name:.....

Signature:..... .....Signature:.....

Date: .... Date:.....

FORM BMS 3

(r. 14(2))

RETURNS FOR USE OF DONATION

Donation Case No:.....Date:.....

TAKE NOTICE that I/We.....(Name of donee) of Identity/Registration No.:.....and Address.....seek to make returns of products donated to us on the.....day of.....by.....(Name of donor).

DESCRIPTION OF THE DONOR

Name: .....

Address:.....

Telephone: .....

Email: .....

Type of institution: .....

Date of incorporation: .....

Reason for donation: .....

DESCRIPTION OF THE DONEE

Name: .....

Address.....

Telephone: .....

Email: .....

Types of institution: .....

Date of incorporation: .....

DESCRIPTION OF THE DONATION

Name: .....

Name of the manufacturer/dealer:.....

Manufacturer date:..... Batch No.:.....

Expiry date:.....

Quantity donated:.....

FORM BMS 4
r.14(3)

RETURNS FORM

DESCRIPTION OF THE DONEE

Name: .....

Address.....

Telephone: .....

Email: .....

Types of institution: .....

Date of incorporation: .....

DESCRIPTION OF THE DONATION

Name: .....

Name of the manufacturer/dealer: .....

Manufacturer date:..... Batch No.:.....

Expiry date: .....

Quantity donated: .....

MODE OF USE

Beneficiaries:.....

Age bracket: .....

Number of beneficiaries: .....

Health outcomes:.....

I hereby declare that the above information is true.

Duly signed by:

Name:.....

Signature:.....

Date:.....

SEIZURE FORM A

(r. 42(2))

(To be used in case of seizure of 'articles' where the 'articles' are to be removed from the premises where they are seized).

To... *(Name and address of the vendor)*.....

.....

.....

Whereas I have reason to believe that the stock of goods detailed below which is/are at the premises of .....

(Name of the premises or owner and address – physical and postal address)

Do not meet the provision(s) of Breast Milk Substitutes (Regulations and Control) Act, 2012.

DETAILS OF THE GOODS

Name of the manufacturer/distributor/importer/trader .....

Postal Address.....

Physical location .....

Goods are marked/branded as follows.....

Physical seal .....

Description of goods .....

Manufacturer date:..... Batch No.:.....

Expiry date:.....

Quantity .....

Now therefore I .....

an authorized officer under section 11 of Breast Milk Substitutes (Regulations and Control) Act, 2012, hereby seize and detain the said goods under section 20 of Breast Milk Substitutes (Regulations and Control) Act.

Name of authorized officer .....

Designation .....

Signature .....

Date .....

OFFICIAL RUBBER STAMP

Manufacturer/distributor/importer/trader/owner/person in possession of the goods

Name .....

Designation .....

Signature ..... Date .....

WITNESS

Name .....

Designation .....

Signature .....

To be filled in duplicate.

SEIZURE FORM B

(r.42(2))

(To be used in case of seizure of 'articles' where the 'articles' are to be kept or stored in the premises where they are seized).

To... *(Name and address of the vendor)*.....

.....

Whereas I have reason to believe that the stock of goods detailed below which is/are at the premises of.....

.....

(Name of the premises or owner and address – physical and postal address)

Do not meet the provision(s) of Breast Milk Substitutes (Regulations and Control) Act, 2012.

DETAILS OF THE GOODS.

Name of the manufacturer/distributor/importer/trader .....

Postal address .....

Physical location .....

Goods are marked/branded as follows .....

Physical seal .....

Description of goods .....

Manufacturer date:..... Batch No.:.....

Expiry date: .....

Quantity .....

Now therefore I .....

an authorized officer under section 11 of Breast Milk Substitutes (Regulations and Control) Act, hereby seize and detain the said goods under section 20 of Breast Milk Substitutes (Regulations and Control) Act and direct you to keep the sealed stock in safe custody subject to such orders as maybe issued subsequently in relation there to.

Be it known to you that removal or alteration or interference in any way with the said article(s) without any authority is an offence under section 20, 21 and 22 of the Breast Milk Substitutes (Regulations and Control) Act.

Name of authorized officer .....

Designation .....

Signature: .....

Date .....

OFFICIAL RUBBER STAMP

Manufacturer/distributor/importer/trader/owner/person in possession of the goods

Name .....

Designation .....

Signature ..... Date .....

WITNESS

Name .....

Designation .....

Signature .....

To be filled in duplicate.

Made on the 5th August, 2021.

MUTAHI KAGWE,
Cabinet Secretary for Health.

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