

Legal Notice No.....

## **THE BREASTMILK SUBSTITUTES (REGULATION AND CONTROL) ACT**

**(No. 34 of 2012)**

*Arrangement of clauses*

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#### **SCHEDULE**

ZERO DRAFT

## **THE BREASTMILK 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 BREASTMILK SUBSTITUTES (GENERAL) REGULATIONS, 2019**

#### **Part I- Preliminary**

Citation	<b>1.</b> These regulations may be cited as the Breastmilk Substitutes (General) Regulations, 2019.
Interpretation	<b>2.</b> In these Regulations, unless the context otherwise requires–  "Act" means the Breastmilk Substitutes (Regulation And Control) Act;  "Authorised officers" means a person appointed under the Act.  "Committee" means the National Committee on Infant and Young Child feeding established under section 4 of the Act;  "Cabinet Secretary" means the Cabinet Secretary for the time being responsible for matters relating to public health;  "Cross-promotion" means a form of marketing where customers of a product or service are targeted with promotion of a related product;  "donation" means a designated product or pre-packaged complementary food offered for charity or humanitarian aid;  "designated product" has the meaning assigned to it under the Act;  "donee" means the person or institution receiving the donation;  "donor" means the person or institution making the donation;  "health worker" has the meaning assigning to it under the Act;  "KS CODEX STAN" means Codex Standard that has been approved as the Kenya standards under the Standards Act;

	<p>"KS EAS" means an East African Standard that has been approved as a Kenya standard under the Standards Act;</p> <p>"KS" means a Kenya Standard approved under the Standards Act; and</p> <p>"Public analyst" means a health officer who examines, reviews, evaluates, or conducts research of designated products and pre-packaged complementary food.</p>
Guiding Principles.	<p><b>3. (1)</b> The guiding principles for the provision of breastfeeding services under these Regulations, binds the authorised officers and all persons whenever any of them–</p> <ul style="list-style-type: none"> <li>(a) applies or interprets any provision of these Regulations; and</li> <li>(b) makes or implements public policy decisions.</li> </ul> <p><b>(2)</b> Without prejudice to sub Regulation (1), an authorised officer shall in the discharge of his or her functions under these Regulations, ensure that–</p> <ul style="list-style-type: none"> <li>(a) in the provision of nutrition services, the best interest of an infant and young child is protected;</li> <li>(b) initiation of breastfeeding of the infant is done within an hour of delivery and exclusive breastfeeding for a period of six (6) months;</li> <li>(c) timely introduction of appropriate pre-packaged complementary food with continued breastfeeding for a period of two (2) years or beyond;</li> <li>(d) where appropriate, breastmilk substitutes and pre-packaged complementary food shall be safe for the consumption of an infant and young child;</li> <li>(e) adequate and accurate information on breastfeeding and infant and young child feeding shall be available to the general public; and</li> <li>(f) Interaction with manufacturers and distributors of breastmilk substitutes and pre-packaged complementary food shall be done in the manner prescribed under the Act and these regulations.</li> </ul>
<b>Part II- Procedures Relating to the Use of Designated Products and Pre-packaged Complementary Food.</b>	
Production.	<p><b>4. (1)</b> The production, preparation and packaging of designated products and pre-packaged complementary food shall be in accordance with the</p>

Cap. 254, 242 and 496.	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.
Sampling and Testing. Cap. 254, 242 and 496.	<b>5.</b> 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.
Packaging.	<b>6.</b> The designated products and the pre-packaged complementary food shall be packaged in accordance with the Act, the relevant written laws, 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).
Importation.	<b>7.</b> (1) A manufacturer or distributor shall not import, offer for sale or sell any designated product or the pre-packaged complementary food if it does not comply with these Regulations, the Act and any other relevant written law.  (2) A person who contravenes the provisions of sub Regulation (1), commits an offence and shall be liable to prosecution in accordance with section 27 of the Act.
Stocking.	<b>8.</b> (1) No person shall stock, distribute, sell or exhibit any food for infant and young child which is expired or whose declared date of expiry reads thirty(30) days before the declared date of expiry.  (2) A person who contravenes the provisions of sub Regulation (1), commits an offence and shall be liable to prosecution in accordance with section 27 of the Act.
Use of Alternative containers from the original.	<b>9.</b> Any person who stocks, distribute, sell or exhibit 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.	<p><b>10.</b> (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.</p> <p>(2) The public analyst referred to under sub Regulation (1), shall upon analysis of the product, issue a certificate of analysis.</p>
<p><b>Part III- Donations of designated products and Pre-Packaged Complementary Food</b></p>	
Application to Donate.	<p><b>11.</b> (1) A person or institution who undertakes to make a donation of a designated product or a 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.</p> <p>(2) An application made under sub-regulation one (1) shall be accompanied by a duly completed <b>Form BMS 1</b> in the first schedule to these Regulations.</p>
Restrictions to Donations.	<p><b>12.</b> (1) A person making a donation under the Act or these Regulations shall not advertise or publicize the making of such donation.</p> <p>(2) The product being donated under sub Regulation (1), shall meet all the requirements of both the Kenyan and International standard as prescribed in law and have at least fifty percent (50 %) shelf life before expiry.</p> <p>(3) The product being donated under sub Regulation (1), shall be in the original container with a clear label marked “Not for Sale”.</p> <p>(4) Donations of designated or pre-packaged complementary food products to charitable children institutions made under the Act and these Regulations shall be for the purpose for which they were donated.</p> <p>(5) Without prejudice to sub Regulation (3), donations made to a charitable children 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 institution with prior written consent of the Committee.</p>

<p>Filing of Returns.</p>	<p><b>13.</b> (1) A Person or institution making donations 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 the prescribed <b>Form BMS 2</b> in the first schedule to these Regulations.</p> <p>(2) A donee upon receipt of the donations under this Act and these Regulations shall within two weeks file returns for use to the Committee in the prescribed <b>Form BMS 3</b> in the first Schedule to these Regulations.</p> <p>(3) A donee shall upon utilization of the donations under sub Regulation (1) file returns with the Committee in the prescribed <b>Form BMS 4</b> in first schedule to these Regulations indicating details of the number of children benefiting from the donations and the health outcomes of those recipients.</p>
<p>Application by Charitable and social Institutions.</p>	<p><b>14.</b> A charitable or social institution who 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.</p>
<p>Uses of Donations.</p>	<p><b>15.</b>(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.</p> <p>(2) No person shall, for the purpose of donating any designated product or a pre-packaged complementary food product, without the written authority 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.</p> <p>(3) A person who contravenes the provisions of sub Regulation (1) and (2), commits an offence and shall be liable to prosecution in accordance with section 27 of the Act.</p>
<p><b>Part IV: Labelling of Designated Products and Pre-Packaged Complementary Food.</b></p>	
<p>Labelling of Designated Products and Pre-packaged Complementary Food.</p>	<p><b>16.</b> (1) The label of a designated product shall in addition to the provisions of the relevant written legislation or Kenya standard, contain the name, address and telephone number of the manufacturer, importer or seller.</p> <p>(2) Notwithstanding sub regulation (1), the label of a designated product and pre-packaged complementary food shall not refer to, promote or advertise any other designated product.</p>
<p>Prohibitions on labelling.</p>	<p><b>17.</b> A label or a container of a designated product or a pre-packaged complementary food shall not contain a photograph, drawing or other</p>

	<p>graphic representation other than for illustrating how the product is to be used.</p>
<p>Labelling of Infant Formula and Follow-up Formula.</p>	<p><b>18.(1)</b> 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 English and 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 and not less than 1.5mm in height preceded by the word "WARNING" in capital letters.</p> <p>"Breast milk is best. Breast milk is ideal for the healthy growth and development of infants and young children. It protects against diarrhea and other illness".</p> <p>(2) The label on any container of infant formula shall—</p> <ul style="list-style-type: none"> <li>(a) not include words such as "maternalised" or "humanised" or similar words or any comparison to breast milk;</li> <li>(b) not use of text, graphics/pictures that may tend to discourage breastfeeding;</li> <li>(c) specify the source of protein; and</li> <li>(d) in case of follow up formula, state that the product shall not be used for infants who are less than six months old.</li> </ul>
<p>Containers of designated and pre-packaged complementary food.</p>	<p><b>19.</b> 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 and Kiswahili language and easily understood graphics indicating—</p> <ul style="list-style-type: none"> <li>(a) instructions for appropriate preparation and use;</li> <li>(b) the age after which the product is recommended for use in numeric figures, in the case of complementary food, shall not be less than six months;</li> <li>(c) a warning about the health risks of improper preparation and of using the product before to the recommended age; and</li> <li>(d) such other particulars as may be subsequently provided from time to time by the Committee.</li> </ul>
<p>Labelling of Formula in Powdered form</p>	<p><b>20.</b> 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 on it, indicate that—</p> <ul style="list-style-type: none"> <li>(a) powdered formula may be contaminated during the manufacturing process or may become contaminated during preparation;</li> </ul>



	<p>(b) it is necessary for formula to be prepared one feed at a time using clean and safe water of at least seventy (70) degrees Celsius; and</p> <p>(c) any unused milk shall be discarded immediately after every feed.</p>
Labelling Requirements for feeding bottles.	<p><b>21.</b> A label, package or a container of a feeding bottle shall indicate in a clear, conspicuous and easily readable manner in English and Kiswahili language the following words in not less than 50% of the size of the largest words on the label not less than 1.5mm in height preceded by the words "IMPORTANT NOTICE" in capital letters:</p> <p>"Breastfeeding is best. Breastfeeding is ideal for the healthy growth and development of infants and young children. It protects against diarrhea and other illness".</p>
Labelling Requirements for teats.	<p><b>22 (1)</b> A label on a package or container of a teat shall not;</p> <p>(a) show any graphic representation other than for illustrating cleaning, the logo of manufacturer or distributor;</p> <p>(b) contain words or images idealising the use of teats;</p> <p>(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.</p> <p>(2) A label, package or a container of a pacifier shall indicate in a clear, conspicuous and easily readable manner in English and Kiswahili language the following words in not less than 50% of the size of the largest words on the label not less than 1.5mm in height preceded by the word "WARNING" in capital letters": "Use of teats can interfere with breastfeeding".</p>
Labelling Requirements for teats and pacifier.	<p><b>23 (1)</b> A label on a package or container of a pacifier shall not;</p> <p>(d) show any graphic representation other than for illustrating cleaning, the logo of manufacturer or distributor;</p> <p>(e) contain words or images idealising the use of teats;</p> <p>(f) Compare the act of suckling the teat to the action, motion or benefits of suckling human breast or physical properties of such human breast.</p> <p>(2) A label, package or a container of a pacifier shall indicate in a clear, conspicuous and easily readable manner in English and Kiswahili language the following words in not less than 50% of the size of the largest words on the label not less than 1.5mm in height preceded by the word "WARNING" in capital letters": "Use of pacifier can interfere with breastfeeding".</p>

<p>Particulars to be inscribed on container</p>	<p><b>23 (1)</b> 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-</p> <p>(a) in English and Kiswahili languages a true statement of the product as to the following matters, that is-</p> <p>(i) composition;</p> <p>(ii) required storage condition;</p> <p>(iii) batch number; and</p> <p>(iv) expiry date;</p> <p>(b) on a label marked on or securely attached to the container the following statement-</p> <p>"Breastfeeding is best. Breastfeeding is ideal for the healthy growth and development of infants and young children. It protects against diarrhea and other illness".</p> <p>(2) Any label affixed to any container of a designated product or a pre-packaged complementary food product as required under subsection (1) of this section shall bear directions for use in English and Kiswahili language and such adequate warnings against the health hazards of inappropriate preparation or use.</p> <p>(3) The statement referred to in subsection (1) of this section shall-</p> <p>(a) be clearly legible and shall appear conspicuously and in a permanent position on the label;</p> <p>(b) specify the name of either the manufacturer, distributor, packer or labeller of the breast-milk substitute or infant formula; and</p> <p>(c) bear an 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.</p>
<p><b>Part V- Interactions between Manufacturers, Distributors and Health Workers</b></p>	
<p>Interactions.</p>	<p><b>24.(1)</b> Any interactions between a manufacturer or distributor with any health worker shall strictly be limited to-</p>

	<ul style="list-style-type: none"> <li>(a) creating awareness about scientific and factual matters on designated products and pre-packaged complementary food;</li> <li>(b) providing samples of designated products and pre-packaged complementary food for professional evaluation; and</li> <li>(c) providing samples of designated products and complementary foods for research of the product.</li> </ul> <p>(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.</p>
Creating Awareness.	<p><b>25.</b> (1) Subject to section 6 (3) (a) of the Act, a manufacturer or distributor who wishes to create awareness about the scientific and factual matters of the breast milk substitute or complimentary food product, shall before commencing interactions with any health worker apply in writing to the Committee for approval.</p> <p>(2)An application made under sub Regulation (1), shall expressly provide for the following information–</p> <ul style="list-style-type: none"> <li>(a) a sworn statement that the interaction does not imply an endorsement of the designated product or pre-packaged complementary food</li> <li>(b) a sworn statement that there is no existing relationship, collaboration or partnership or intended relationship, collaboration or partnership with the health worker;</li> <li>(c) particulars of the health workers targeted for awareness;</li> <li>(d) proposed public venue;</li> <li>(e) sample of the designated product or pre-packaged complementary food to be used during the interaction;</li> <li>(f) a certificate of analysis from a public analyst in Kenya;</li> <li>(g) a detailed report on scientific findings and evidence based research of the benefits of the product;</li> <li>(h) a peer reviewed scientific information of the product;</li> <li>(i) proof that the designated product or pre-packaged complementary food to be used during the interaction meets the national and international standards; and</li> <li>(j) any other relevant document requested by the Committee.</li> </ul>
Professional evaluation.	<p><b>26.</b> (1) Any interactions between a manufacturer or distributor and a health worker for purposes of professional evaluation of a designated product or pre-packaged complementary food shall commence after the approval of the Committee.</p>

	<p>(2) Any health worker participating in the interaction under sub Regulation (1) shall–</p> <ul style="list-style-type: none"> <li>(a) before commencing the interaction seek written approval from the Committee; and</li> <li>(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.</li> </ul>
Research of Product.	<p><b>27.</b> (1) A health worker who intends to carry out research on a designated product or pre-packaged complementary food and intends to request for samples from a manufacturer or distributor shall apply in writing to the Committee.</p> <p>(2) The application referred to under sub Regulation (1), shall be accompanied by–</p> <ul style="list-style-type: none"> <li>(a) an approved research protocol;</li> <li>(b) an ethical approval from a competent and recognised authority in Kenya;</li> <li>(c) a certificate of analysis;</li> <li>(d) proof of use in country of origin if the product is not made in Kenya;</li> <li>(e) ethical approval from a competent authority if the product is originating outside of Kenya; and</li> <li>(f) any other document the Committee may require.</li> </ul>
Formal Record.	<p><b>28. (1)</b> Any health worker who wishes to participate in any interaction with a manufacturer or distributor, for 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 to the Committee on request.</p> <p>(2) The formal record referred to in sub Regulation (1) shall contain such information as may be directed by the Committee.</p>
Restrictions to Interactions.	<p><b>29. (1)</b> A manufacturer or distributor during the interaction with a health worker shall not–</p> <ul style="list-style-type: none"> <li>(a) distribute any promotional material or items;</li> <li>(b) give misleading information as prohibited by the Breastfeeding Act;</li> <li>(c) engage in activities without the approval of the Committee;</li> </ul>

	<ul style="list-style-type: none"> <li>(d) distribute any samples of designated or pre-packaged complementary food product;</li> <li>(e) hold promotional activity at an alternative venue not approved; and</li> <li>(f) brand the venue in any way to promote infant formula.</li> </ul>
Cross-Promotion.	<p><b>30.</b> (1) A manufacturer or distributor of a designated product or a pre-packaged complementary food shall not engage in cross-promotion.</p> <p>(2) A person who contravenes the provisions of sub Regulation (1), commits an offence and shall be liable to prosecution in accordance with section 27 of the Act.</p>
Information Inserts.	<p><b>31.</b> (1) A manufacturer or distributor of a designated product or a pre-packaged complementary food, shall not insert any other information, beyond the scope of the packaged product for purposes of consumer information or education.</p> <p>(2) A manufacturer or distributor of a designated product or a pre-packaged complementary food, shall not collaborate with another manufacturer or distributor of any other product other than a designated product or a pre-packaged complementary food, to insert any other information, beyond the scope of the packaged product for purposes of consumer information or education.</p> <p>(3) A person who contravenes the provisions of sub Regulation (1), commits an offence and shall be liable to prosecution in accordance with section 27 of the Act.</p>
Advertisement.	<p><b>32.</b> 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—</p> <ul style="list-style-type: none"> <li>(a) written publication, television or radio broadcast, film or electronic transmission, including the internet, video or telephone;</li> <li>(b) displays, signs, symbols, colours, billboards or notices; or</li> <li>(c) exhibition of pictures or models;</li> </ul> <p>Commits an offence and shall be liable to prosecution in accordance with section 27 of the Act.</p>
Demonstration for use of a pre-packaged complementary food product.	<p><b>33.</b> The method used by a health worker during demonstrations for use of pre-packaged complementary food product shall be either one-on-one or in a group and shall contain the following information;</p> <ul style="list-style-type: none"> <li>(a) the benefits and superiority of breastfeeding;</li> </ul>

	<ul style="list-style-type: none"> <li>(b) the value of exclusive breastfeeding for the first six months followed by sustained breastfeeding for at least two years;</li> <li>(c) the proper preparation and use of the product;</li> <li>(d) the importance of feeding infants with an open cup and spoon; and</li> <li>(e) how pre-packaged complementary food can easily be prepared at home using local ingredients.</li> </ul>
Procedure for demonstration for use of infant and follow-up formula	<p><b>34. (1)</b> The method used by a health worker during demonstrations for use of infant formula shall be one-on-one in a secluded area and shall—</p> <ul style="list-style-type: none"> <li>(a) be in the original container of manufacture;</li> <li>(b) conceal the brand name;</li> <li>(c) maintain hygiene; and</li> <li>(d) follow the manufacturer’s instruction for preparation.</li> </ul> <p>(2) A health worker while conducting a demonstration under sub Regulation (1), shall inform the infant's mother on—</p> <ul style="list-style-type: none"> <li>(a) the benefits and superiority of breastfeeding;</li> <li>(b) the value of exclusive breastfeeding for the first six months followed by sustained breastfeeding for at least two years and optimal maternal nutrition;</li> <li>(c) the difficulty of returning to breastfeeding after a period of artificial feeding.</li> <li>(d) the negative effects of artificial feeding on lactation and how early introduction of pre-packaged complementary food interferes with breastfeeding;</li> <li>(e) instructions on proper preparation and use of the product;</li> <li>(f) the approximate financial cost of adequate feeding of an infant with the product;</li> <li>(g) the health hazards of bottle feeding</li> <li>(h) the importance of feeding an infant with an open cup and spoon; and</li> <li>(i) how to feed an infant with an open cup and spoon.</li> </ul>
<b>Part VI- Enforcement</b>	
Authorised Persons	<b>35.</b> In addition to Section 11 of the Act, an authorised officer may include a health worker, custom officer, police officer or officers from the body responsible for Standards.

Inspection.	<p><b>36.</b> An Authorised officer, shall subject to section 12 of the Act, conduct an inspection in the prescribed <b>Form 5</b> in the first Schedule to these Regulations.</p>
Confidential Information.	<p><b>37. (1)</b> An officer who divulges confidential information obtained during the course of investigations conducted under these Regulations, the Act or any other law commits an offence.</p> <p>(2) Despite sub Regulation (1), this Regulation does not apply to information that is—</p> <ul style="list-style-type: none"> <li>(a) given as evidence in proceedings taken under the Act or any other law relating to consumer protection;</li> <li>(b) given by the authorised officer as part of a report;</li> <li>(c) prepared for the purpose of an investigation; or</li> <li>(d) a matter of public record or is otherwise in the public domain.</li> </ul> <p>(3) A person who contravenes the provisions of this Regulation, commits an offence and shall be liable to prosecution in accordance to section 27 of the Act.</p>
Access to Breasmilk substitutes.	<p><b>38.</b> A manufacturer or distributor, upon request shall produce any prescribed designated product or pre-packaged complementary food to an authorised officer</p>
Seizures.	<p><b>39. (1)</b> 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—</p> <ul style="list-style-type: none"> <li>(a) prohibited goods; and</li> <li>(b) not being sold by an authorised manufacturer, wholesaler, distributor or retailer of goods,</li> </ul> <p>the officer may, without laying any information or obtaining any warrant, seize and remove those goods.</p> <p>(2) Seizure of goods under these Regulations and Act by an authorized officer shall be in accordance to Form A and B prescribed in the Schedule to these Regulations.</p>
Conflict of Interest.	<p><b>40. (1)</b>A health worker who has any interest whether pecuniary or business interest in any designated product or pre-packaged complementary food shall disclose the nature of interest to the Committee, on commencement of employment and as soon as the relevant facts have come to his or her knowledge in accordance with the Public Officers Ethics Act, No. 4 of 2003.</p>

	<p>(2) A disclosure of interest under sub-regulation (1) shall be recorded by the Committee.</p> <p>(3) A health worker having made such a disclosure shall not be present during any interactions under the Act.</p>
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**FIRST SCHEDULE**

**Forms**



**Form BMS 1**

**Application for Donation**

**FORM BMS 1**

**APPLICATION FOR DONATION**



**Donate 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**

**Name:**  
**Signature:**  
**Date:**

**DONEE**

**Name:**  
**Signature:**  
**Date:**

ZERO DRAFT



**FORM BMS 2**  
**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**

Name:  
Signature:  
Date:

**DONOR**

Name:  
Signature:  
Date:



**FORM BMS 3**

**RETURNS FOR USE OF 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:**.....

ZERO DRAFT



**FORM BMS 4**  
**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**

(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 .....

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.

ZERO DRAFT





**Form BMS 4  
SEIZURE FORM B**

(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.

**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.....

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.



**Form BMS 5**

**INSPECTION FORM**

(To be used in case of inspection 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.

**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.....

Quantity.....

Now therefore I .....

an authorized officer under section 11 of Breast Milk Substitutes (REGULATIONS AND CONTROL) ACT, 2012 hereby inspects the said goods under section 12 and 13 of Breast Milk Substitutes (REGULATIONS AND CONTROL) ACT 2012.

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.

ZERO DRAFT