

**EXHIBIT NO. 1 TO MASTER AGREEMENT  
SPECIFICATIONS AND ADDITIONAL TERMS**

**1. SCOPE OF WORK**

- 1.1. Rebates paid to Participating Entities under the Master Agreement are limited to Infant Formula purchased under the federally funded WIC Program with USDA, FNS funds.
- 1.2. Participating Entities shall make decisions affecting this Contract by consensus. A majority vote will be used if consensus cannot be reached.
- 1.3. Contractor shall provide the products offered on Exhibit 2 (A) and/or Exhibit 2 (B) Bid Sheets and offer a per unit rebate for each unit size and physical form of the Primary Milk-Based and/or Soy-Based Infant Formula it manufactures that meets the specifications below in Section Two.
- 1.4. Contract terms shall not be negotiated with respect to the following:
  - a. Length or number of extension periods:
  - b. Rebate amounts that will apply to the Master Agreement and any extension periods:  
and
  - c. The method by which the rebates will be calculated.

**2. FORMULA SPECIFICATIONS**

- 2.1 The New Master Agreement Milk-Based Infant Formula shall have a Rebate which is offered under DASPS 2205-18 and shall meet the following specifications:
  - a. The Milk-Based Infant Formula shall meet the definition of an infant formula, as stated in section 201(z) of the federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(z)), the requirements for an infant formula under section 412 of the federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 350a), and the regulations at 21 CFR parts 106 and 107.
  - b. The Milk-Based Infant Formula shall satisfy all requirements under 7 CFR 246.10(e)(1)(iii) and 7 CFR 246.10(e)(2)(iii).
  - c. The Milk-Based Infant Formula shall contain at least 10 milligrams of iron per liter at standard dilution and supply 67 kilocalories per 100 milliliters (i.e. approximately 20 kilocalories per fluid ounce of infant formula) at standard dilution.
  - d. The Milk-Based Infant Formula shall be nutritionally complete not requiring the addition of any ingredients other than water prior to being served in a liquid state.
  - e. The Milk-Based Infant Formula shall be available in liquid concentrate, powdered concentrate and ready-to-feed.

- 2.2 The Master Agreement for Soy-Based Infant Formula shall have a Rebate which is offered under DASPS-2205-18 shall meet the following specifications:
- a. The Soy-Based Infant Formula shall meet the definition of an infant formula, as stated in section 201(z) of the federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(z)), the requirements for an infant formula under section 412 of the federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 350a), and the regulations at 21 CFR parts 106 and 107.
  - b. The Soy-Based Infant Formula shall satisfy all requirements under 7 CFR 246.10(e)(1)(iii) and 7 CFR 246.10(e)(2)(iii).
  - c. The Soy-Based Infant Formula shall contain at least 10 milligrams of iron per liter at standard dilution and supply 67 kilocalories per 100 milliliters (i.e. approximately 20 kilocalories per fluid ounce of infant formula) at standard dilution.
  - d. The Soy-Based Infant Formula shall be nutritionally complete not requiring the addition of any ingredients other than water prior to being served in a liquid state.
  - e. The Soy-Based Infant Formula shall be available in liquid concentrate, powdered concentrate and ready-to-feed.
- 2.3 Contractor shall agree to supply and pay a “per unit” Rebate on any new Milk-Based or Soy-Based Infant Formula it introduces to the marketplace after the Master Agreement is awarded. Contractor agrees to provide the wholesale price of any new products at the time the product is added to the Master Agreement. The rebate for infant formula added to the Master Agreement after the start date (new and existing) will be calculated using the Wholesale Price of the formula at the time the formula is approved for issuance by the Participating Entity.
- 2.4 Within ten (10) business days of Master Agreement Award, the Contractor shall furnish the State of Oregon with a list of their Milk-Based Infant Formulas and/or Soy-Based Infant Formulas that meets the FDA requirements for an infant formula. These formulas shall be included in the Master Agreement. The list shall not include WIC eligible Exempt Infant Formula or WIC-Eligible Medical Foods. The list shall include the Contractor’s nationally published best full truckload wholesale price at the time of the Bid opening for each unit size and physical form of infant formula.
- 2.5 The Rebate offered for each unit size and physical form of the Primary Milk-Based or Soy-Based Infant Formula, as specified on Attachment I (A) and/or Attachment I (B) Bid Price Sheets, shall be converted to a Percent Discount and used to calculate the Rebate for the corresponding physical form of Milk-Based or Soy-Based Contract Infant Formula. The Percent Discount is multiplied by the Bidder’s nationally published best full truckload wholesale price to establish the rebate for the Contract infant formulas.

### **3. USE OF MASTER AGREEMENT(S) INFANT FORMULA**

Participating Entities shall approve the Contractor's list of Master Agreement for Infant Formula shall be submitted per Section 2.4 above. The Master Agreement Infant Formula shall be the first choice of issuance to infants covered by this Master Agreement. Participating Entities are not required to approve or issue the manufacturer's entire product line of Milk-Based or Soy-Based contracted Infant Formula.

Participating Entities may only issue non-contract brands of infant formula with medical documentation and according to the Participating Entity's agency policy outlined in Exhibit E of Solicitation DASPS-2205-18. Participation and usage data provided in the IFB does not necessarily reflect actual issuance and redemption that will occur under the new Contract.

#### **4. CONTRACT INFANT FORMULA AVAILABILITY**

- 4.1 By October 1, 2018, the Master Agreement Infant Formula shall be in full statewide distribution. Full statewide distribution means the formula is readily available from wholesale suppliers that supply WIC authorized retail vendors for each Participating Entity.
- 4.2 The Contractor shall manufacture and make available Master Agreement Infant Formula in sufficient quantity to serve WIC participants of the Participating Entities through their wholesale distribution system.

#### **5. WHOLESALER NOTIFICATION**

- 5.1 Within two weeks of the award of this Contract, the Contractor shall contact wholesale suppliers in the geographic service locations of all of the Participating Entities to notify them of the Contract award and the implementation date of the Master Agreement for Infant Formula under the Master Agreement(s). Participating Entities will provide lists and/or mailing labels of wholesale suppliers, if requested.

#### **6. PRODUCT CHANGES**

- 6.1 Contractor shall give the Lead State of Oregon and Participating Entities at least Ninety (90) calendar days advance written notice of planned changes in formulation, product name, reconstituted amount per unit, product packaging including size, weight and/or label, and discontinuation of their Master Agreement Infant Formula and other Infant Formulas in their product line. The Contractor shall provide electronically product labels showing any changes.
- 6.2 Contractor shall notify the Lead State of Oregon and Participating Entity to the plan and execute a communication strategy regarding product changes. Notify the Lead State of Oregon and the Participating Entity when product change information shall be distributed to WIC clinics, authorized retail vendors and/or the medical community.
- 6.3 Contractor shall communicate with the Lead State of Oregon and the Participating Entity to provide prorated Rebates (i.e. the same Percent Discounts as remitted for the Master Agreement for Infant Formula) should any of the Milk-Based or Soy-Based Contract Infant Formula be discontinued, reformulated or produced in a different can

size, or should any new product be introduced which is designed to take the place of the Milk-Based or Soy-Based Contract Infant Formula. If the Contractor discontinues production of the Master Agreement Infant Formula, it shall provide a rebate that yields the same net cost per ounce for the replacement formula.

## **7. WHOLESALE PRICE CHANGES**

7.1 Contractor shall provide written notification to the Lead State of Oregon and all Participating Entities regarding any wholesale price changes. An amendment shall be created to memorialize the change. Notification shall be in writing and shall be provided to all customers at the same time that other customers are notified of the change. The notification shall include both the effective date and the amount of the change for all products meeting the Master Agreement Infant Formula definition.

7.2 Throughout the term of the Master Agreement, any increase or decrease in the wholesale price per unit shall be matched by a cent-for-cent increase or decrease in the Rebate per unit and be applied the first day of the month following the approved wholesale price changes. This applies to all products meeting the Contract Infant Formula definition.

7.3 Changes in rebate amounts (other than cent-for-cent adjustments) are prohibited for the full term of the Master Agreement, including any Master Agreement extensions, per USDA, FNS regulations.

## **8 FAILURE TO SUPPLY SUFFICIENT QUANTITIES**

8.1 Supply problems are defined as incidents when product is not available to wholesalers and chain store distribution centers.

8.2 A Participating Entity shall notify the Contractor within twenty-four (24) hours of any report that the Milk-Based or Soy-Based Contracted Infant Formula is not available or available in an inadequate supply to meet demand through a wholesale supplier in their service location. The Contractor will investigate the alleged supply problem and notify both the Master Agreement manager and the Participating Entity of its findings within forty-eight (48) hours.

8.3 Contractor shall notify the lead State of Oregon and all Participating Entities immediately of the supply problem. The Master Agreement Administrator shall work with the Contractor to immediately remedy the supply problem through direct shipments of product to affected areas, substitution of another product in the Contractor's product-line, or any other immediate solution approved by the Contract Administrator.

8.4 If the Contractor is unable to supply sufficient quantities of a contract brand infant formula, Lead State of Oregon and Participating Entities shall first issue the same brand of a Contract Infant Formula in a different physical form to address the shortage as long as supply for that form is sufficiently available.

- 8.5 If both the Lead State of Oregon and Participating Entity is not satisfied with Contractor's remedy proposed in Section 8.3 above, Contractor shall pay the contracted rebate amount for alternate FDA approved infant formulas substituted the Participating Entities until the supply problem is resolved.
- 8.6 Contractor is not responsible for lack of Milk-Based and/or Soy-Based Contract Infant Formula inventory at the retail level due to the failure of individual retail vendors to order stock from their wholesale supplier at the appropriate levels.

## **9 MONTHLY INVOICES AND DOCUMENTATION**

- 9.1 Each Participating Entity shall send the Contractor a monthly invoice with supporting documentation. The invoice and documentation shall list the number of units that qualify for a Rebate, the Rebate per unit, and the dollar amount due thirty (30) calendar days from the date of the invoice receipt.
- 9.2 The first monthly invoice shall be no earlier than November 15, 2018 reflecting information about Contract Infant Formula that qualified for a Rebate in October 2018.
- 9.3 Invoices will continue past the Master Agreement expiration date to account for all Food Instruments (FI) issued during the term of the Master Agreement. This is necessary because FI may be valid to be paid up to ninety (90) days after the issuance date although some Participating Entities use a shortened time period (e.g. 60 days). For example, FI issued the last day of the Master Agreement (September 30) may be valid to be paid up to ninety (90) days later (December 29).
- 9.4 The monthly invoice shall list the name and address of the person to whom the Rebate payment shall be sent. Descriptions of each Participating Entity's method for determining a reasonable estimate or an actual count of the number of units that qualify for a Rebate are in Exhibit E.
- 9.5 Participating Entity documentation used to support the monthly invoice shall vary in format due to differences in information systems. Rebate invoices for March through August 2017 for each Participating Entity are included in Exhibit E of the Solicitation
- 9.6 Participating Entities reserve the right to change the format of the monthly invoice and associated documentation as needed due to system changes.
- 9.7 When possible, Participating Entities shall provide an electronic data file to validate the monthly invoice. The minimum information that shall be provide is: food instrument number, pseudo vendor identification number, food package identification, product name, number of units authorized to purchase, effective date of food instrument, redemption date of food instrument, and redeemed amount. Participating Entities shall work with Contractor regarding available data elements.

## **10 REBATE PAYMENT**

Contractor shall make Rebate payments directly to each Participating Entity. The Rebate will be calculated using the Rebate per unit in effect on the first day of the month the FI was paid. Rebate payments are due thirty (30) calendar days from the receipt of invoice.

#### **11 LATE REBATE PAYMENT**

Contractor shall be assessed a penalty for late payments. The penalty will be one (1) percent of the invoiced amount.

#### **12 INVOICE DISPUTES OR ERRORS**

12.1 All invoice disputes shall be resolved directly between the Contractor and Participating Entity on a state-by-state basis.

12.2 All invoice disputes shall be settled by closeout of the federal fiscal year in which the dispute occurs.

12.3 The Contractor shall notify the Participating Entity of any dispute or believed error within ninety (90) calendar days of receiving the invoice. The notice shall be in writing and shall describe the specific nature of the dispute or believed error. Failure by the Contractor to notify the Participating Entity within the ninety (90) calendar day period shall constitute a waiver and release of any dispute or error.

12.4 The Participating Entity shall notify the Contractor of any invoice error in the rebate calculation within sixty (60) calendar days of issuing the invoice. The notice shall be in writing and shall describe the specific error. Participating Entities agree to resolve errors promptly.

12.5 The Contractor shall not withhold or offset (payment reduction from invoiced amount) rebate payments under any circumstances.

12.6 Participating Entities agree to review and validate invoices. The Participating Entity shall work with the Contractor to determine the best method of repayment if a refund is due the Contractor.

12.7 If an invoice dispute occurs about which the Participating Entity and Contractor cannot reach agreement, the Participating Entity or Contractor may request an independent review to be conducted by either party.

#### **13 RECORD RETENTION AND AUDITS**

13.1 Contractor and the Participating Entities shall maintain documentation relevant to Rebate invoices and payments for six (6) years after the expiration of the Master Agreement.

13.2 Contractor's records relevant to rebate invoices and payments shall be subject to review or audit, at any reasonable time and upon reasonable notice, by the State of Oregon, Participating Entities, the USDA, Office of the Inspector General, Comptroller General of the United States, or their representatives.

13.3 Participating Entity FI data used in the calculation of units that qualify for a rebate and working documents and reports used in the preparation of monthly invoices shall be

subject to review or audit, at any reasonable time and upon reasonable notice, by the Contractor or their representatives as agreed upon by both parties.

13.4 Participating Entity data that is confidential under federal, tribal or state law is not subject to review or audit by the Contractor or their representatives.

#### **14 DEVIATIONS FROM THE SCOPE OF THE CONTRACT**

Contractor shall not approach a Participating Entity with any offer that deviates in any manner from the scope of this Contract.

#### **15 DISASTER/SUPPLY INTERRUPTION CONTINGENCY PLANS**

15.1 Contractor shall provide the Lead State of Oregon with a supply source interruption contingency plan within thirty (30) calendar days of the Contract award. The plan shall include a description of how the Contractor shall ensure Contract Infant Formula shall be available to WIC authorized retail vendors in the event of a supply source interruption or other circumstance that affects the Contractor's ability to provide the Contract Infant Formula through its normal wholesale delivery system.

15.2 Within forty eight (48) hours of a disaster, when retail food delivery systems may be interrupted, Participating Entities shall notify the contractor of the disaster if it is in the geographic areas served by the Participating Entity. Within twenty-four (24) hours of being notified of the disaster and interruption of the retail food delivery system, the Contractor shall notify the Participating Entity whether it is supplying Milk-Based or Soy-Based Master Agreement Infant Formula to any public or private disaster relief organizations in the geographic area of the disaster and the name of the organizations and their primary contact.

#### **16 INFANT FORMULA SAMPLE**

Contractor shall NOT be required to provide Infant Formula samples to any of the Participating Entities, in accordance with USDA, FNS Guidelines.

#### **17 TRANSITION COMMUNICATION PLAN**

17.1 Contractor shall provide the Lead State of Oregon with a transition communication plan within thirty (30) calendar days of contract award. The plan shall include a description of how the new Contractor shall assist Participating Entities with communicating information about the new Master Agreement.

17.2 Contractor shall make available advertising art/graphics in suitable electronic format to Participating Entities to be used for the development of materials used to communicate information on the new Contract.

17.3 Participating Entities shall work cooperatively with the Contractor to assure written communication occurs with health care providers, hospitals and retailers thirty (30) calendar days prior to Contract start date.

17.4 Food Instruments with a “first day of use” date prior to October 1, 2018 will be rebated under Washinton, Contract no. 05411 (Milk-Based) and Washington, Contract no. 02715 (Soy-Based). Food Instruments with a “first day of use” date October 1, 2018 or later shall be rebated under new State of Oregon Master Agreement. Contractors should anticipate a transition period with a change to a Master Agreement Infant Formula. The transition process may vary significantly between Participating Entities. It is probable that for some Participating Entities, the number of cans reflected on rebate invoices in the first few months shall not be reflective of usage through the term of the Master Agreement.

## **18 COMMUNICATION AND ADVERTISING**

18.1 Contractor shall not distribute any written communication connecting the WIC Program and the Milk-Based and/or Soy-Based Contract Infant Formula without prior review and written consent by the Lead State of Oregon and Participating Entity(s) in the planned distribution area.

18.2 Contractor shall not advertise or publish information concerning this Master Agreement in any form or media without prior review and written consent from the Master Agreement Administrator.

18.3 Participating Entities will work cooperatively with the Contractor to ensure that documents printed and distributed by WIC Programs are accurate.

18.4 Use of WIC Service Marks:

- a. Manufacturer acknowledges that the WIC Acronym and the WIC Logo are service marks owned by the Department of Agriculture (USDA), and that all rights therein and goodwill pertaining thereto belong exclusively to USDA per Supplement Food Policy Division (SFPD) Policy Memo 2009-1, dated December 31, 2008 and FNS Instruction 800-2 dated, June 21, 1992.
- b. Manufacturers shall not use these service marks in any manner on its goods or their containers or packaging or on tags or labels affixed thereto. Manufacturer also shall not use the WIC Logo in advertising or other promotional materials (collectively: “advertising”).
- c. Manufacturer shall not use the WIC Acronym in advertising in any manner that is likely to cause confusion, mistake, or deception as to the affiliation, connection, or association of Manufacturer with the WIC Program, or as to the sponsorship or approval of Manufacturer’s goods, services, advertising, or commercial activities, including nutritional message(s), by the WIC Program, USDA, or the Participating Entity.
- d. Manufacturer shall include the following statement with any use of the WIC Acronym in advertising: “WIC is a registered service mark of the U.S. Department of Agriculture for USDA’s Special Supplemental Nutrition Program for Women, Infants and Children.”

## **19 CONFIDENTIALITY**

Contractor may not access any records identifying WIC participants by name and/or address, per 7 CFR 246.26(d). Contractor shall not have access to any information about a retailer that individually identifies the vendor, except for the vendor's name, address, website, email, store type and authorization status per 7 CFR 246.26(e).

**20 FULL NUTRITIONAL BENEFIT (FNB)**

The Participating Entities shall issue infant formula in accordance with 7 CFR 246.10(e)(1) through (e)(3) and (e)(9). In addition, the Participating Entities shall, if necessary provide the full nutritional benefit (FNB), use the methodology outlined in 7 CFR 246.10(h) when issuing infant formula. The Participating Entities reserves the right to issue infant formula using this methodology at their discretion.

**21 SOVEREIGN IMMUNITY**

A Participating Entity does not waive its sovereign immunity by entering into the Master Agreement and fully retains all immunities and defenses provided by law with respect to any action based on the Master Agreement.

- 22** The intent of this section is to indicate that a Participating Entity does not waive any sovereign immunity it may otherwise retain, merely by virtue of its participation in this Master Agreement. This Master Agreement does not otherwise attempt to describe or explain what sovereign immunity, if any, may have been retained by any specific Participating Entity

**PRODUCT RECALL**

If there is a recall of any of the Contract Infant Formulas, the Contractor shall immediately notify the Lead State Master Agreement Administrator and one designee for each Participating Entity by telephone, email and facsimile. This notification shall include the following information for the formula being recalled: the name of the specific formula (formulation), the container size(s), the form (powder, liquid concentrate, and/or ready-to-feed), the lot number(s), the expiration date(s), the inventory code(s), the address where the product should be returned, the specific problem or concern with the product, and the name, phone number and email address of the Contractor's employee who is the contact person with respect to the recall. If WIC participants are unable to exchange recalled formula at the store from which it was purchased, the Contractor shall replace or reimburse the Participating Entities, free of charge, for any containers of recalled contract brand infant formula provided to WIC participants through food instruments or free samples.