Specifications for SWC #437:
WIC, Infant Formula

Listing of Attachments/Exhibits:

- Attachment I: TN WIC Exempt (Therapeutic) Formula List
- Attachment III: Pricing Worksheet*
- Attachment IV: Compliance Form*
- Exhibit I: WIC Infant Formula Rebate Invoices Jan. 2013-June 2013
- Exhibit II: Formula Data Jan. 2013-June 2013
- Exhibit III: Total Participation

*Requires Vendor Completion

Nondiscrimination

No person shall be excluded from participation in, be denied benefits of, be discriminate against in the admission or access to, or be discriminated against in treatment or employment in the State's contracted programs or activities on the grounds of handicapped and/or disability, age, race, creed, color, religion, sex, national origin, or any other classification protected by federal or Tennessee state constitutional or statutory law; nor shall they be excluded from participation in, be denied benefits of, or be otherwise subjected to discrimination in the performance of contracts with the State or in the employment practices of the State's contractors. Accordingly all vendors entering in contracts with the State shall, upon request, be required to show proof of such nondiscrimination and to post in conspicuous places, available to all employees and applicants, notices of nondiscrimination. The State of Tennessee, Department of Health has designated the following office to coordinate compliance with the nondiscrimination requirements of the State of Tennessee, Title VI of the Civil Right Acts of 1964, the Americans with Disabilities Act of 1990, and applicable federal regulations:

Director Mike Gaines
Office of Compliance
Department of Health
Andrew Johnson tower, 5th floor
710 James Robertson Parkway
Nashville, Tennessee 37243
Phone: 615-532-5042
**Assistance to Bidders with Disability**

Any individuals with disabilities who wish to participate in public meetings such as scheduled pre-response conferences or other scheduled functions should contact the Central Procurement Office to discuss any auxiliary aids or services needed to facilitate such participation. Such contact may be in person, by writing, telephonically, or otherwise, and should be made no less than seven (7) days prior to the scheduled event to allow time for the Central Procurement Office to provide such aid or service.

1. **Introduction:**

The State will consider bids for rebate offers for all physical forms (concentrated, powder, and RTF) of a milk-based infant formula that meets the requirements of 7 C.F.R. § 246.10(e)(1)(iii) and (2)(iii) and is suitable for the routine issuance to the majority of generally healthy, full term infants. In addition, the State agency will, if necessary, to provide the full nutritional benefit (FNB), use the methodology outlined in 7 CFR 246.10(h) in the WIC Program regulations when issuing infant formula. The State is seeking a vendor to supply and provide a rebate for, iron-fortified infant milk-based and soy-based formulas in all physical forms, liquid concentrate, powder, and ready-to-feed in their infant formula product line through the state WIC agency's retail distribution system.

2. **Definitions:**

   a. **Clinics** - Health facilities where applicants for WIC services are certified eligible for the WIC program and receive WIC services.

   b. **Contract Brand Infant Formula** - All infant formulas (except exempt Tennessee therapeutic formulas as set forth in Attachment I: TN WIC Exempt) produced by the manufacturer awarded the contract which are the liquid concentrate milk-based, iron-fortified formulas and any other product line formulas in liquid concentrate form; powdered, milk-based, iron-fortified formula, and any other product line formulas in powdered form; and ready-to-feed, milk-based, iron-fortified formula and any other product line formulas in ready-to-feed form.

   c. **Contractor/Vendor** - The selected bidder who is awarded a contract for infant formulas and rebates as outlined in this Invitation to Bid (ITB).

   d. **Estimated Monthly Number of Cans** - The projected number of cans to be purchased on a monthly basis by product type, physical form and container size.

   e. **Exempt Infant Formula** - Infant formula which meets the requirements for an exempt infant formula under section 412(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(h) and the regulations at 21 C.F.R. parts 106 and 107.
f. **FNS** - Food and Nutrition Services, United States Department of Agriculture (USDA).

g. **Infant Formula** - A food which meets the definition of an infant formula in section 201(z) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321(z)) and which meets the requirements for an infant formula under section 412(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §350a) and the regulations at 21 C.F.R. parts 106 and 107.

h. **Invoices** - Monthly bill submitted by the State to the successful bidder for payment of the rebate.

i. **Issue Date** - This is the date the WIC voucher is issued to the participant.

j. **Net Monthly Wholesale Cost to the State for Milk-Based Formula (for evaluation purpose only)** - The total of the "net per can wholesale cost to the State" multiplied by the standardized number of units" to be purchased (See Attachment III: Pricing Worksheet).

k. **Net per Can Cost to the State** - The best full truckload national wholesale price per can less rebate offer per can.

l. **Partial Redemptions** - Food instruments issued for the full nutrition benefit that are redeemed for less than 59.5 percent of the maximum allowable reimbursement level amount for each physical form of contract brand infant formula.

m. **Primary Contract Infant Formula** - The specific infant formula which will become the 1st choice for issuance and for which the contractor submits a bid in response to this solicitation.

n. **Quotation Sheet** - The terms “Quotation Sheet” and “Price Sheet” are used interchangeably.

o. **Rebate** - Amount payable to Tennessee Department of Health for each can of contract brand infant formula authorized on a redeemed voucher and purchased by the participant (see §246.16a(k))

p. **Redeemed Voucher** - A negotiable food instrument which has been exchanged by a participant at a WIC retail vendor for authorized foods and infant formulas identified on the voucher and submitted to the bank-processing firm by the WIC retail vendor for payment and paid by the state WIC agency.

q. **Standardized Number of Unit(s)** - The average monthly number of infants using each physical form is multiplied by the maximum monthly allowable number of ounces for each form (as allowed under §246.10(e)(9)(Table1)), 246.16a(c)(5)(i) and divided by the corresponding unit size (i.e., number of ounces per unit being bid).
r. **State WIC Agency or Agency** - State of Tennessee Department of Health Division of Family Health and Wellness, Special Supplemental Nutrition Program for Women Infants and Children.

s. **Therapeutic Formula** - Any formula issued to a WIC participant that requires a written order from a physician or other licensed professional authorized by Tennessee law to write prescriptions. Therapeutic formula may include both exempt and non-exempt infant formulas (Attachment I: TN WIC Exempt).

t. **Truckload Price** - Lowest national wholesale cost per unit for a full truckload of the infant formula on the date of the bid opening (§246.16a(c)(5)).

u. **Voucher** - A negotiable food instrument issued by the clinics that lists authorized foods and infant formulas that may be exchanged for such foods and infant formulas at a participating WIC retail vendor. The terms voucher, negotiable food instrument, and food instrument are used interchangeably.

v. **WIC** - Special Supplemental Nutrition Program for Women, Infants and Children.

w. **Non Contract Brand Infant Formula** – Any non-exempt infant formula that is produced by a manufacturer other than the contracted vendor and any exempt infant formula produced by the contracted vendor/manufacturer and any other manufacturer.

x. **WIC Retail Vendors** - Individuals or business entities that:

1. Operate one or more retail establishment such as a grocery store or pharmacy.

2. Are authorized by the State WIC Agency to exchange vouchers for WIC authorized foods and infant formulas.

3. Are under agreement with the State WIC Agency.

3. **Certification and Assurance of Compliance (Attachment IV: Compliance Form):**

   Bidders shall attach written certification and assurance of the bidder's compliance with:

   1. Registration with the Secretary of the United States, Department of Health and Human Services under Federal Food, Drug, and Cosmetic Act (21 U.S.C. §301 et seq.) and bidder's products are in compliance with federal regulations.

   2. The Federal Food, Drug, and Cosmetic Act and regulations issued pursuant to such act.
3. The Tennessee Department of Health's requirement that all infant formulas identified will carry the label of the bidder.

4. **Competitive Bid Rebate System for Retail Distribution:**

In order to meet participant needs, the State is seeking to assure adequate supply of infant formula products at all WIC retail vendors statewide that meet the requirements of 7 C.F.R. § 246.12. The Pricing Worksheet (Attachment III) shall contain the rebate offer per can on the following physical forms of a milk-based infant formula that is suitable for the routine issuance to the majority of generally healthy, full term infants.

- 12.1 to 13.0 liquid concentrate
- 12.4, 12.5, 12.7, or 12.9 ounce powdered. For purposes of the State's evaluation of cost, the various can sizes will be converted to a standardized unit for milk-based iron-Fortified formula.
- 32 or 33.8 ounce ready-to-feed

5. **Responsibilities:**

The Contractor shall:

1. Pay rebate to the State as described herein.

2. Provide the State with advance written notification of any changes in product price (i.e. any increase or decrease) at least 60 calendar days prior to the effective date of such change(s).

3. Provide the State with advance written notification of any changes in product packaging, size, product labels, product information and/or reformulation of infant formula. This notice shall be provided at least 90 calendar days prior to the effective date of such change(s).

4. In the event the contractor introduces an infant formula designed to replace the primary contract infant formula(s) referenced in the contract, the contractor shall provide such formulas at the same net wholesale cost per fluid ounce cost as the original formula.

5. The rebate for each of the milk-based or soy-based infant formulas shall yield the same percent discount on the wholesale cost as to the rebate for the primary contract brand of infant formula for concentrate, powdered and ready-to-feed infant formulas. Additionally, rebates will apply to any new formulas added to the contractor’s product line after initial contract date which yield the same percent discount as the
corresponding physical form of the primary contract brand based on the wholesale price in effect the time the State agency approved for issuance.

The Tennessee Department of Health shall:

1. Have present, the names of the awarded bidder's infant formula on the negotiable food instruments to be used by the WIC program participants to purchase infant formula in accordance with 7 C.F.R. § 246.10 (e)(1) thru (e)(3) and (e)(9).

2. Submit on a monthly basis a detailed invoice reflecting the number of cans (brand names) authorized on fully and partially redeemed vouchers from the WIC program's authorized WIC vendors and the rebate to be remitted to the state. All redeemed vouchers for contract brand infant formula will be evaluated to determine which vouchers were partially redeemed using 59.5 percent of the maximum "maximum allowable reimbursement level amount" for each physical form. The "maximum allowable reimbursement level amount" on contract brand infant formula is based on the amount that is set to be high enough to cover the highest price redeemed vouchers of the smallest authorized WIC vendor. This allows for the wide variations in pricing between west and east Tennessee vendors. The payment by the contractor is made after the receipt of the invoice sent by the Tennessee Department of Health. The monthly rebate invoice will include the total number of cans calculated based on full and partial redemptions authorized on redeemed vouchers multiplied by the rebate offer per can.

3. Provide supporting documentation to verify the accuracy of the invoice on a monthly basis. Such documentation will include a comparison of redeemed vouchers issued for the full nutrition benefit (FNB) and partially redeemed vouchers.

4. Validate and correct any overbilling error for the infant formula rebate that occurs.

5. Upon resolution of a rebate invoice dispute, pay any funds due the contractor within a period not to exceed 45 calendar days. All rebate disputes must be resolved by the close-out of the federal fiscal year in which the dispute occurred.

6. Notify all WIC sites, contracted WIC vendors and physicians of the contractor's brands of allowable infant formulas under this contract to be exclusive infant formulas of the Tennessee WIC program.

7. Not provide contractor access to:
   a. Any records identifying participant's name and/or address
   b. Any information about retail vendors that individually identifies the vendor, except for vendor's name, website, address, email address, store type, telephone number, and authorization status.
8. Reserve the rounding up option in order to provide the full nutrition benefit (FNB) when the FNB can only be met by using the rounding up methodology (7 C.F.R. § 246.10(h)).

6. **Payment terms:**

The contractor shall:

1. Remit to the State the total monthly rebate in full as determined by the State to be due, based on the rebate offered on the ITB’s Pricing Worksheet (Attachment III) as will be adjusted for any price increases or decreases for the number of cans authorized on redeemed vouchers for infant formula manufactured by the contractor. Payment shall be made by the contractor within 30 calendar days from the receipt of an invoice from the agency detailing the number of cans authorized on redeemed vouchers for infant formula manufactured by the contractor purchased by the participants. Payment shall be wire transferred to the agency into an account number provided by the agency.

2. Notify the agency by email or telephone at least one (1) business day prior to transmitting wire transfer to the agency. Contact person:

   WIC accountant: Karen Kopinski  
   Department of Health, Fiscal Services  
   615-532-8502  
   Karin.kopinski@tn.gov

3. Remit to the agency the rebate due in full for all cans of the contractor's infant formula purchased with redeemed vouchers during the contract period. Because the WIC Program issues three (3) months of food instruments at a time, the rebate shall continue to apply to any authorized redeemed vouchers for the contractor's infant formula for up to 120 days following the end of the contract period.

4. Work with the Tennessee Department of Health to settle all disputes prior to the closeout of the Federal Fiscal Year in which the dispute occurred. Any dispute not settled by the closeout of the Federal Fiscal Year in which the dispute occurred shall constitute a waiver and release of any dispute, error, correction, or change in the agency’s rebate invoice that would otherwise have been raised by the contractor except in the case of an audit or a situation where negligence, errors beyond human control, and/or illegal activity prevented the contractor from being able to identify the error, correction, or change in the agencies rebate invoice.

5. Not withhold, under any circumstances, any rebate payments due the agency, nor shall the contractor interrupt or reduce rebate payments during the period that the resolution of any invoice dispute is pending.
6. In the event the contractor fails to meet the requirements provided in this agreement, the State will be harmed. The actual damages that the State will sustain in the event of, and by reason of, such failure to perform are uncertain, and are extremely difficult and impractical to ascertain and determine. By contracting with the State, the contractor agrees and acknowledges that the contractor shall be assessed liquidated damages for any failure to timely pay any rebate payment as follows: Interest shall accrue on any outstanding rebate payment amount due and payable to the state at the prime rate plus one and one half percentage points (1.5%).

The Tennessee Department of Health shall:

1. Work with the contractor to settle all disputes prior to the closeout of the Federal Fiscal Year in which the dispute occurred. Any dispute not settled by the closeout of the Federal Fiscal Year in which the dispute occurred shall constitute a waiver and release of any dispute, error, correction, or change in the contractor’s rebate payment that would otherwise have been raised by the agency, except in the case of an audit or a situation where negligence, errors beyond human control, and/or illegal activity prevented the agency from being able to identify the error, correction, or change in the contractor’s rebate payment.

7. Monitoring:

   Inspection:

   1. The contractor shall, at all times during the period that this contract is in force, assure to authorized personnel of the Tennessee Department of Health, USDA, the Tennessee Comptroller of the Treasury, and Comptroller General of the United States, the right, during the contractor's normal business hours, to inspect or otherwise evaluate the quality, appropriateness, and timeliness of the services provided, determine the amounts payable under the contract, and inspect the contractor's rebate cost records at such intervals as the State and/or USDA deems necessary.

   Program Reports:

   2. As requested, the contractor shall meet with the agency to review the progress and performance of the current contract. The contractor shall address any concerns regarding billing procedures at these meetings. If the State should require information related to the contract, the contractor will provide such information within ten (10) working days from the agency's written request at no additional cost to the State.

   The contractor must have a management information system sufficient to provide the state with up-to-date detailed information and program reports if needed excluding any
data that is deemed confidential, proprietary or trademarked. The data must be provided in an electronic format.

The State must have a management information system sufficient to provide the contractor with up-to-date detailed information and program reports if needed excluding any data that is deemed confidential, proprietary or trademarked. The data must be provided in an electronic format.

Use of WIC Service Marks as referenced in FNS Policy Memo #2009-1:

3. Manufacturer acknowledges the WIC acronym and the WIC logo are service marks owned by the U.S. Department of Agriculture (USDA), and all rights therein, and goodwill pertaining thereto, belong exclusively to USDA. Manufacturer shall not use these service marks in any manner on its goods, containers, packaging, tags, or labels affixed thereto.

Manufacturer also shall not use the WIC logo in advertising or other promotional materials (collectively: "advertising"). 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 State agency.

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."