



Special Formula and Medical Documentation

Part 1: WIC Formula Categories

Presented by: Denice Vance, MS, RD, LD, CLC

Date: February 6, 2017



We Protect Lives.

Objectives

Following this presentation attendees will be able to:

- Understand WIC formula categories and the federal regulations that guide our program policies
- Use state created resources as a reference when determining formula categories

We Protect Lives.

Federal Terms/Definitions

- Contract Formula
- Non-Contract Formula
- Exempt Infant Formula
- WIC-Eligible Nutritionals

We Protect Lives.

Contract Formula

- All infant formulas, except exempt infant formulas, produced by the manufacturer awarded the infant formula rebate contract
- Infants participating in the GA WIC program who require a standard infant formula must be provided one of the contract formulas
 - Gerber Good Start Gentle
 - Gerber Good Start Soothe
 - Gerber Good Start Soy

We Protect Lives.

Non-Contract/Exempt Formula

- Non-Contract - all infant formula, including exempt infant formula, that is not covered by an infant formula rebate contract
- Exempt Infant Formula - infant formula that 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 CFR parts 106 and 107](#)

We Protect Lives.

New Search Help | More About 21CFR

[Code of Federal Regulations]
 [Title 21, Volume 2]
 [Revised as of April 1, 2016]
 [CITE: 21CFR107.50]

TITLE 21--FOOD AND DRUGS
 CHAPTER I--FOOD AND DRUG ADMINISTRATION
 DEPARTMENT OF HEALTH AND HUMAN SERVICES
 SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION

PART 107 -- INFANT FORMULA
 Subpart C--Exempt Infant Formulas

Sec. 107.50 Terms and conditions.

(a) Terms and conditions. Section 412(f)(1) of the act exempts from the requirements of section 412(a), (b), and (c)(1)(A) of the act infant formulas that are represented and labeled for use by an infant who has an inborn error of metabolism or low birth weight or who otherwise has an **unusual** medical or dietary problem, if such formulas comply with regulations prescribed by the Secretary. The regulations in this subpart establish the terms and conditions that a manufacturer must meet with respect to such infant formulas.

“...labeled for use by an infant who has an inborn error of metabolism or low birth weight or who has an otherwise **unusual** medical or dietary problem...”

We Protect Lives.

Non-Contract/Exempt Formula

- Any issuance of an authorized, non-contract or exempt infant formula requires appropriate medical documentation
- All infant formulas, including contract formula, require medical documentation to be issued to a child or woman participant

We Protect Lives.

Non-Contract Rice Added Infant Formula

For the issuance of Enfamil A.R., the following two conditions are required:

- Diagnosis of gastroesophageal reflux disease (GERD)
- One of the following conditions:
 - Pneumonia, tube feeding, GERD surgery (fundoplication), weight loss, or poor weight gain (drop of at least one weight channel on growth chart)
 - If weight is not provided, issuance will be based on weight obtained at WIC clinic

We Protect Lives.

Federal Terms/Definitions


- **WIC-Eligible Nutritionals** - certain enteral products that are specifically formulated to provide nutritional support for individuals with a qualifying condition, when the use of conventional foods is precluded, restricted, or inadequate

We Protect Lives.

What is "Special Formula"???

- Specific to the GA WIC Program
- Refers to any formula that is not included in the state's infant formula rebate contract
 - Non-contract infant formula
 - Exempt infant formula
 - WIC-eligible nutritionals (children and women products)


We Protect Lives.



Georgia WIC Formula Guide

A Reference for WIC Approved Formulas

Revised January 2017 (See Highlighted Text)



Contract formulas not requiring medical documentation for infants (< 12 months old):

Approved Contract Milk Based Formula: Gerber Good Start Gentle	Approved Contract Soy Based Formula: Gerber Good Start Soy
Approved Contract Lactose-Reduced Formula: Gerber Good Start Soothe	

Non-Contract formulas requiring medical documentation:

Approved Non-Contract Rice-Added Formula:
 Enfamil A.R.

The following two conditions must exist prior to issuance of a Non-Contract Rice Added Formula:

- 1) Diagnosis of gastroesophageal reflux disease (GERD) and one of the following conditions:
- 2) Pneumonia, tube feeding, GERD surgery (fundoplication), weight loss, or poor weight gain (drop of at least one weight channel on growth chart). Note: If weight is not provided, issuance will be based on weight obtained at WIC clinic.

Follow WIC Medical Documentation Guidelines for All Other Formulas

Georgia WIC **DOES NOT APPROVE** the following formulas for distribution:


Any Organic Formula	Similac Expert Care 24
Enfagrow Toddler Next Step (All Flavors)	Similac for Spit-Up *
Enfagrow Toddler Transitions	Similac for Supplementation *
Enfagrow Toddler Transitions Gentle	Similac Go & Grow *
Enfagrow Toddler Transitions Soy	Similac Go & Grow Sensitive *
Enfamil 24	Similac Pro-Advanced
Enfamil (Inspira)	Similac Pro-Sensitive
Enfamil for Supplementation	Similac Pure Bliss (Infant and Toddler)
Enfamil Gentlease	Similac Sensitive *
Enfamil Infant	Similac Soy Isomil
Enfamil Newborn	Similac Total Comfort *
Enfamil ProSobee	Stage 2 Gerber Good Start (Gentle and Soothe)
Enfamil ReadyToGo	Stage 3 Gerber Good Start Grow
Gerber Good Start Gentle for Supplementation	Stage 3 Gerber Good Start Soy
Gerber Good Start Protect	*Non-GMO formulations are also not approved
Similac Advance *	Store brand milk-based, soy, lactose-free, lactose reduced, or rice added formulas
Similac Expert Care for Diarrhea	

Questions or concerns please contact:

Denise Vance, MS, RD, LD, CLC
 Nutrition Program Specialist
 Georgia WIC Program
 (404) 657-2884
Denise.Vance@dph.ga.gov

Kylie Crane, RD, LD
 Nutrition Coordinator
 Georgia Chapter, American Academy of Pediatrics
 (404) 881-5093
kcraus@aappa.org

For the complete list of Georgia WIC Approved Formulas/Medical Foods, please visit us online at wic.ga.gov and click on the "Health Care Provider Information" link.





Georgia WIC Approved Formulas and Nutritionals



Gerber Good Start Soy	Nestle Nutrition/Gerber
Gerber Good Start Soothe	Nestle Nutrition/Gerber

Non-Contract Formulas/Nutritionals Requiring Medical Documentation:

Formula	Manufacturer	Formula	Manufacturer	Formula	Manufacturer
Acerflex	Nutricia	Calcio XD	Abbott Nutrition	Enfamil	Mead Johnson
Add-Ins	Nutricia	Carnation	Nestle Nutrition	EnfaCare	Johnson
Alfamino Infant	Nestle Nutrition	Carnation Breakfast Essentials	Nestle Nutrition	Human Milk Fortifier	Mead Johnson
Alfamino Junior	Nestle Nutrition	Carnation Breakfast Essentials, No Sugar Added	Nestle Nutrition	Acidified Liquid	Mead Johnson
A-Soy	PBM Products	Compleat	Nestle Nutrition	Premature 20 with iron	Mead Johnson
Benebcalorie	Nestle Nutrition	Compleat Pediatric	Nestle Nutrition	Premature 24 with iron	Mead Johnson
Beneprotein	Nestle Nutrition	Compleat Pediatric Reduced Calorie	Nestle Nutrition	Premature 30 with iron	Mead Johnson
Boost	Nestle Nutrition	Complete Amino Acid Mix	Nutricia North America	Enfaport	Mead Johnson
Boost Breeze	Nestle Nutrition	Complex MSUD Amino Acid Bars	Applied Nutrition Corporation	Ensure Clear	Abbott Nutrition
Boost Glucose Control	Nestle Nutrition	Cyclinex 1	Abbott Nutrition	Ensure High Protein	Abbott Nutrition
Boost Kid Essentials 1.0	Nestle Nutrition	Cyclinex 2	Abbott Nutrition	Ensure Original	Abbott Nutrition
Boost Kid Essentials 1.5	Nestle Nutrition	Duocel	Nutricia	Ensure Plus	Abbott Nutrition
Boost Kid Essentials 1.5 w/ fiber	Nestle Nutrition	EleCare (for Infants)	Abbott Nutrition	Ensure Pudding	Abbott Nutrition
Boost Nutritional Pudding	Nestle Nutrition	EleCare Jr	Abbott Nutrition	EO26	Nutricia
Bonnet Plus	Nestle Nutrition	Enfamil A.R.	Mead Johnson	Splash	Nutricia
Bright Beginning Soy	PBM Products			Fiber Source HN	Nestle Nutrition
				Gerber Extensive HA	Nestle Nutrition/Gerber

Revised January 2017 Page 1 of 5



GA WIC Approved Formulary

- The local agency may only authorize the issuance of formula and nutritionals available on the GA WIC Approved Formulary
- Formulas and nutritionals not currently on the GA WIC Approved Formulary can be considered for addition to the formulary by formal request from the medical provider or other applicable party
 - Written documentation of participant need or a market demand
 - Documentation of USDA authorization is required
 - Upon State WIC Office Nutrition Unit review the request may be denied or approved

We Protect Lives.

Thank You for Your Participation!

Denice Vance, MS, RD, LD, CLC
GA WIC Program
404-656-9868

Denice.Vance@dph.ga.gov

We Protect Lives.

Georgia WIC Formula Guide

A Reference for WIC Approved Formulas

Revised January 2017 (See Highlighted Text)

Human milk is considered to be the gold standard for infant feeding

Contract formulas <u>not</u> requiring medical documentation for infants (< 12 months old):	
<p style="text-align: center;"><u>Approved Contract Milk Based Formula:</u> Gerber Good Start Gentle</p> <p style="text-align: center;"><u>Approved Contract Lactose-Reduced Formula:</u> Gerber Good Start Soothe</p>	<p style="text-align: center;"><u>Approved Contract Soy Based Formula:</u> Gerber Good Start Soy</p>
Non-Contract formulas <u>requiring</u> medical documentation:	
<p><u>Approved Non-Contract Rice-Added Formula:</u> Enfamil A.R.</p> <p>The following two conditions must exist prior to issuance of a Non-Contract Rice Added Formula:</p> <ol style="list-style-type: none"> 1) Diagnosis of gastroesophageal reflux disease (GERD) and one of the following conditions: 2) Pneumonia, tube feeding, GERD surgery (fundoplication), weight loss, or poor weight gain (drop of at least one weight channel on growth chart). Note: If weight is not provided, issuance will be based on weight obtained at WIC clinic. <p style="text-align: center;">Follow WIC Medical Documentation Guidelines for All Other Formulas</p>	

Georgia WIC **DOES NOT APPROVE** the following formulas for distribution:

Any Organic Formula	Similac Expert Care 24
Enfagrow Toddler Next Step (All Flavors)	Similac for Spit-Up *
Enfagrow Toddler Transitions	Similac for Supplementation *
Enfagrow Toddler Transitions Gentlelease	Similac Go & Grow *
Enfagrow Toddler Transitions Soy	Similac Go & Grow Sensitive *
Enfamil 24	Similac Pro-Advance
Enfamil Enspire	Similac Pro-Sensitive
Enfamil for Supplementing	Similac Pure Bliss (Infant and Toddler)
Enfamil Gentlelease	Similac Sensitive *
Enfamil Infant	Similac Soy Isomil
Enfamil Newborn	Similac Total Comfort *
Enfamil ProSobee	Stage 2 Gerber Good Start (Gentle and Soothe)
Enfamil Reguline	Stage 3 Gerber Good Start Grow
Gerber Good Start Gentle for Supplementing	Stage 3 Gerber Good Start Soy
Gerber Good Start Protect	*Non-GMO formulations are also not approved
Similac Advance *	Store brand milk-based, soy, lactose-free, lactose reduced, or rice added formulas
Similac Expect Care for Diarrhea	

Questions or concerns please contact:

Denice Vance, MS, RD, LD, CLC
Nutrition Program Specialist
Georgia WIC Program
(404) 657-2884
Denice.Vance@dph.ga.gov

Kylia Crane, RD, LD
Nutrition Coordinator
Georgia Chapter, American Academy of Pediatrics
(404) 881-5093
kcrane@gaaap.org

Georgia WIC Approved Formulas and Nutritionals

Contract Infant Formula	
Gerber Good Start Gentle	Nestlé Nutrition/Gerber
Gerber Good Start Soy	Nestlé Nutrition/Gerber
Gerber Good Start Soothe	Nestlé Nutrition/Gerber

Non-Contract Formulas/Nutritionals Requiring Medical Documentation:

Formula	Manufacturer
Acerflex	Nutricia
Add-Ins	Nutricia
Alfamino Infant	Nestlé Nutrition
Alfamino Junior	Nestlé Nutrition
A-Soy	PBM Products
Benecalorie	Nestlé Nutrition
Beneprotein	Nestlé Nutrition
Boost	Nestlé Nutrition
Boost Breeze	Nestlé Nutrition
Boost Glucose Control	Nestlé Nutrition
Boost Kid Essentials 1.0	Nestlé Nutrition
Boost Kid Essentials 1.5	Nestlé Nutrition
Boost Kid Essentials 1.5 w / fiber	Nestlé Nutrition
Boost Nutritional Pudding	Nestlé Nutrition
Boost Plus	Nestlé Nutrition
Bright Beginning Soy	PBM Products

Formula	Manufacturer
Calcilo XD	Abbott Nutrition
Carnation Breakfast Essentials	Nestlé Nutrition
Carnation Breakfast Essentials, No Sugar Added	Nestlé Nutrition
Compleat	Nestlé Nutrition
Compleat Pediatric	Nestlé Nutrition
Compleat Pediatric Reduced Calorie	Nestlé Nutrition
Complete Amino Acid Mix	Nutricia North America
Complex MSUD Amino Acid Bars	Applied Nutrition Corporation
Cyclinex 1	Abbott Nutrition
Cyclinex 2	Abbott Nutrition
Duocal	Nutricia
EleCare (for Infants)	Abbott Nutrition
EleCare Jr	Abbott Nutrition
Enfamil A.R.	Mead Johnson

Formula	Manufacturer
Enfamil EnfaCare	Mead Johnson
Enfamil Human Milk Fortifier Acidified Liquid	Mead Johnson
Enfamil Premature 20 with iron	Mead Johnson
Enfamil Premature 24 with iron	Mead Johnson
Enfamil Premature 30 with iron	Mead Johnson
Enfaport	Mead Johnson
Ensure Clear	Abbott Nutrition
Ensure High Protein	Abbott Nutrition
Ensure Original	Abbott Nutrition
Ensure Plus	Abbott Nutrition
Ensure Pudding	Abbott Nutrition
EO28 Splash	Nutricia
Fiber Source HN	Nestlé Nutrition
Gerber Extensive HA	Nestlé Nutrition/Gerber

Georgia WIC Approved Formulas and Nutritionals

Formula	Manufacturer
Gerber Good Start Premature 24	Nestlé Nutrition
Glucerna	Abbott Nutrition
Glutarex-1	Abbott Nutrition
Glutarex-2	Abbott Nutrition
Hominex-1	Abbott Nutrition
Hominex-2	Abbott Nutrition
Introlite	Abbott Nutrition
IsoSource 1.5	Nestlé Nutrition
IsoSource HN	Nestlé Nutrition
I-Valex-1	Abbott Nutrition
I-Valex-2	Abbott Nutrition
Jevity	Abbott Nutrition
KetoCal 3:1	Nutricia
KetoCal 4:1	Nutricia
Ketonex-1	Abbott Nutrition
Ketonex-2	Abbott Nutrition
KetoVie	Cambrooke Therapeutics
KetoVolve	Solace Nutrition
L-Emental	Hormel Health Labs
L-Emental Hepatic	Hormel Health Labs
L-Emental Pediatric	Hormel Health Labs
Lipistart	Vitaflow

Formula	Manufacturer
Lo*Pro	Med-Diet Labs
Lophlex LQ	Nutricia
MCT Oil	Nestlé Nutrition
MCT Procal	Vitaflow
Methionaid	Nutricia
Microlipid	Nestlé Nutrition
Monogen	Nutricia
MSUD Analog	Nutricia
MSUD Maxamaid	Nutricia
MSUD Maxamum	Nutricia
MSUD-1	Nutricia
MSUD-2	Nutricia
Neocate Infant DHA & ARA	Nutricia
Neocate Junior	Nutricia
Neocate Junior with Prebiotics	Nutricia
Neocate Nutra	Nutricia
Neocate Splash	Nutricia
Neocate Syneo Infant	Nutricia
Nepro with Carb Steady	Abbott Nutrition
Nitro-Pro	Hormel Health Labs
NovaSource Renal	Nestle Nutrition
Nutramigen	Mead Johnson
Nutramigen with Enflora LGG Toddler	Mead Johnson

Formula	Manufacturer
Nutramigen with Enflora LGG	Mead Johnson
Nutren 1.0	Nestle Nutrition
Nutren 1.0 with Fiber	Nestlé Nutrition
Nutren 1.5	Nestlé Nutrition
Nutren 2.0	Nestlé Nutrition
Glytrol	Nestlé Nutrition
Nutren Junior	Nestlé Nutrition
Nutren Junior Fiber	Nestlé Nutrition
Nutren Pulmonary	Nestlé Nutrition
Replete with Fiber	Nestlé Nutrition
NutriHep	Nestlé Nutrition
Osmolite 1.0	Abbott Nutrition
Osmolite 1.2	Abbott Nutrition
PediaSure	Abbott Nutrition
PediaSure 1.5 Cal	Abbott Nutrition
PediaSure 1.5 Cal with fiber	Abbott Nutrition
PediaSure Enteral	Abbott Nutrition
PediaSure Enteral w/Fiber and scFOS	Abbott Nutrition
PediaSure Peptide 1.0 Cal	Abbott Nutrition

Georgia WIC Approved Formulas and Nutritionals

Formula	Manufacturer
PediaSure Peptide 1.5 Cal	Abbott Nutrition
PediaSure w/Fiber	Abbott Nutrition
Pepdite Junior	Nutricia North America
Peptamen	Nestlé Nutrition
Peptamen 1.5	Nestlé Nutrition
Peptamen AF	Nestlé Nutrition
Peptamen Jr. HP	Nestlé Nutrition
Peptamen Junior	Nestlé Nutrition
Peptamen Junior 1.5	Nestlé Nutrition
Peptamen Junior Fiber	Nestlé Nutrition
Peptamen Junior with Prebio	Nestlé Nutrition
Perative	Abbott Nutrition
Periflex Advance	Nutricia
Periflex Early Years	Nutricia North America
Periflex Infant	Nutricia North America
Periflex LQ (previously Xphe Maxamum)	Nutricia North America
Phenex-1	Abbott Nutrition
Phenex-2	Abbott Nutrition

Formula	Manufacturer
PhenylAde 40Drink Mix	Applied Nutrition Corporation
PhenylAde 60Drink Mix	Applied Nutrition Corporation
PhenylAde Amino Acid Bars	Applied Nutrition Corporation
PhenylAde Amino Acid Blend	Applied Nutrition Corporation
PhenylAde Drink Mixes	Applied Nutrition Corporation
PhenylAde Essential Drink	Applied Nutrition Corporation
PhenylAde MTE Amino Acid Blend	Applied Nutrition Corporation
Phenyl-Free 2	Mead Johnson
Phenyl-Free 2HP	Mead Johnson
Phlexy – 10 Bar	Nutricia
Phlexy – 10 Capsules	Nutricia
Phlexy – 10 Drink Mix	Nutricia
PKU Periflex Junior Plus	Nutricia North America
PKU-Express	Vitaflo Limited
PKU-Gel	Vitaflo Limited
Polycal	Nutricia
Portagen	Mead Johnson
Pregestimil	Mead Johnson

Formula	Manufacturer
Pregestimil 24	Mead Johnson
Product 3232 A	Mead Johnson
ProMod Liquid Protein	Abbott Nutrition
Promote	Abbott Nutrition
Promote with Fiber	Abbott Nutrition
Pro-Peptide	Hormel Health Labs
Pro-Peptide for Kids	Hormel Health Labs
Pro-Peptide VHN	Hormel Health Labs
Pro-Phree	Abbott Nutrition
Propimex-1	Abbott Nutrition
Propimex-2	Abbott Nutrition
Protifar	Nutricia North America
ProViMin	Abbott Nutrition
Pulmocare	Abbott Nutrition
PurAmino	Mead Johnson
PurAmino Toddler	Mead Johnson
RCF	Abbott Nutrition
RE/GEN	Nutra/Balance
Renalcal	Nestlé Nutrition
RenaStart	Vitaflo
Resource 2.0	Nestlé Nutrition

Georgia WIC Approved Formulas and Nutritionals

Formula	Manufacturer
Scandical Calorie Booster	Aptalis
Scandishake	Aptalis
Scandishake Lactose Free	Aptalis
Scandishake Sugar Free	Aptalis
Similac Alimentum	Abbott Nutrition
Similac Expert Care Alimentum	Abbott Nutrition
Similac NeoSure	Abbott Nutrition
Similac Expert Care NeoSure	Abbott Nutrition
Similac Human Milk Fortifier	Abbott Nutrition
Similac PM 60/40	Abbott Nutrition
Similac Special Care with Iron 20	Abbott Nutrition
Similac Special Care with Iron 24	Abbott Nutrition
Similac Special Care with Iron 30	Abbott Nutrition
SolCarb	Solace
Suplena with Carb Steady	Abbott Nutrition
Tolerex	Nestlé Nutrition
TwoCal HN	Abbott Nutrition
Tyrex-1	Abbott Nutrition
Tyrex-2	Abbott Nutrition

Formula	Manufacturer
UCD Anamix Junior	Nutricia
UCD-2	Nutricia
Vivonex Pediatric	Nestlé Nutrition
Vivonex Plus	Nestlé Nutrition
Vivonex RTF	Nestlé Nutrition
Vivonex T.E.N.	Nestlé Nutrition
XLeu Maxamaid	Nutricia
XLeu Maxamum	Nutricia
XLys, XTrp Maxamaid	Nutricia
XLys, XTrp Maxamum	Nutricia
XMet Maxamaid	Nutricia
XMet Maxamum	Nutricia
XMTVI Maxamaid	Nutricia
XMTVI Maxamum	Nutricia
XPhe , XTyr Maxamaid	Nutricia
XPhe Maxamaid	Nutricia
XPTM Analog	Nutricia

Georgia WIC Approved Formulas and Nutritionals

- Ready-to-feed formula may be indicated in limited documented cases, such as:
 - Unsanitary or restricted water supply
 - Inadequate refrigeration
 - Caregiver has a documented condition which inhibits the proper dilution of concentrated or powder formula.
 - For participants in Food Package III with a qualifying medical condition and who are receiving exempt infant formulas or nutritionals (a) if the ready-to-feed form better accommodates the participant's medical condition or (b) if the ready-to-feed form improves the participant's compliance in consuming the prescribed formula.
- If a health care provider with prescriptive authority orders a product that is not on this list, contact the Nutrition Unit to determine whether the product may be authorized for distribution through Georgia WIC.
- Special formulas may be acquired through the Nutrition Unit. See Georgia WIC Procedures Manual, Food Package Section for appropriate procedure and forms.

This institution is an equal opportunity provider.