

Code compliance and purchasing formula

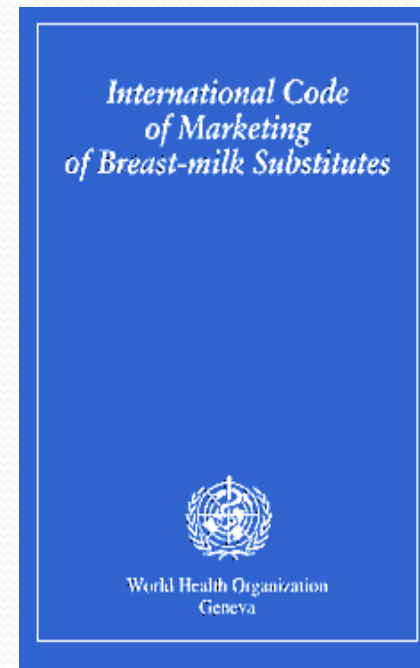
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What is the Code?

- The Code is a set of recommendations from the World Health Organization to regulate the marketing of breastmilk substitutes, feeding bottles, and artificial nipples
- The Code was formulated in response to the realization that poor infant feeding practices were negatively affecting the growth, health and development of children, and were a major cause of morbidity and mortality in infants and young children



What is the Code?

- The Code aims to contribute "to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding, and by ensuring the proper use of breastmilk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution" (Article 1).
- The Code advocates that babies be breastfed.
- If babies are not breastfed, the Code says that they be fed safely on the best available nutritional alternative.



What is the Code?

- The Code refers to marketing practices of manufacturers and distributors, not the use of the product
 - We know that bottles and formula are sometimes necessary
- A tool to reduce deceptive and unethical marketing of products covered under the Code
- Such marketing may induce mothers to avoid or abandon breastfeeding and may convince mothers and healthcare providers that breastmilk and formula are equivalent

Deceptive marketing example

- This ingredient is not derived from human milk
- It is fermented from a non-pathogenic strain of *E coli*



“Discover the first and only formula with 2’-FL Human Milk Oligosaccharide, an immune-nourishing prebiotic previously only found* in breast milk.”

A Quick Guide to WHO Code Basics

What does the Code cover?

- Formula milk
- Any food or drink that would substitute for breastfeeding eg teas or foods aimed at babies under six months, or formula aimed at any age
- Bottles
- Teats or nipples

Who is expected to follow the Code?

- Manufacturers, distributors, and retailers of any of the above items
- Health care workers, both professionals and volunteers
- Health care facilities—hospitals, clinics, etc

What must be on the label?

- Labels must be in the local language
- Information must include the hazards associated with artificial feeding
- Labels cannot use idealising language or images eg a happy baby sleeping, or a protective shield suggesting baby is in a protected bubble against disease

What IS allowed under the Code?

- ✓ Use of formula with safe preparation, for babies who need it
- ✓ Sale of products with technical information eg “125 ml polycarbonate bottle”
- ✓ Scientific and factual information for health professionals eg contains certain proteins
- ✓ Accurate information on safe formula preparation is required on all labels

What is NOT allowed under the Code?

- ✗ Promotion to parents: advertising, free samples
- ✗ Promotion to health professionals: gifts, free samples
- ✗ Promotion in health facilities: posters, free formula, gifts
- ✗ Promotion of unsuitable products for babies (such as sweetened condensed milk)



The Code has 11 articles and 17 resolutions

1. Aim - The Code aims to protect and promote breastfeeding by ensuring appropriate marketing and distribution of breastmilk substitutes.
 2. Scope - The Code applies to breastmilk substitutes, when marketed or otherwise represented as a partial or total replacement for breastmilk. These breastmilk substitutes can include food and beverages such as:
 - infant formula
 - other milk products
 - cereals for infants
 - vegetable mixes
 - baby teas and juices
 - follow-up milks.
- The Code also includes feeding bottles and artificial nipples
3. Advertising - No advertising of above products to the public.

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The Code

4. Samples - No free samples to mothers, their families or health workers.
5. Health care facilities - No promotion of products, i.e. no product displays, posters or distribution of promotional materials. No use of mothercraft nurses or similar company-paid personnel.
6. Health workers - No gifts or samples to health workers. Product information must be factual and scientific.

What the Code says:

3. No promotion of products through health care facilities, including free or low-cost formula
4. No contact between marketing personnel and mothers
5. No gifts or personal samples to health care professionals



6. No words or pictures idealizing artificial feeding, including pictures of infants on the labels of the products

What the companies do:

- Provide cash to hospitals through formula contracts in return for accepting free formula and distributing formula-containing discharge bags
- Give nurses a name badge holder and stethoscope name tag bearing the brand name of the formula such that the formula name is at eye level when the nurse leans over to deliver care
- Provide hospitals with crib cards bearing the name of the formula
- Supply hospitals with formula-containing gift bags labeled for breastfeeding mothers
- Have unrestricted access to the maternity floor as they supply food and gifts to the staff; these salesmen are in plain view of patients, ignoring vendor policies
- Entice nurses to promote formula by providing free in-services, offering prizes in contests for those who use the most formula, supply food and expensive dinners, give nurses presents, give nurses and physicians a full year's supply of formula when they have babies, provide physicians with ski trips, Club Med memberships, and tickets to sporting events
- Buy the good will of health care professionals to make it easier to promote formula. Gift-giving and pseudo-friendship forms a loyalty to the formula salesman and a defensive attitude in the health care provider
- The Ross Employee Manual states, ... "Never underestimate the role of nurses. If they are sold and serviced properly, they can be strong allies. A nurse who supports Ross is like another salesman."
- Make claims that their product performs like breast milk
- Advertise on television



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The Code

7. Supplies - No free or low-cost supplies of breastmilk substitutes to any part of the health care system.
8. Information - Information and educational materials must explain the benefits of breastfeeding, the health hazards associated with bottle feeding, and the costs of using infant formula.



The Code

9. Labels - Product labels must clearly state the superiority of breastfeeding, the need for the advice of a health worker and a warning about health hazards. No pictures of infants, or other pictures or text idealizing the use of infant formula.




10. Unsuitable products, such as sweetened condensed milk, should not be promoted for babies. All products should be of a high quality

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Experts agree on the many benefits of breast milk. If you choose to use infant formula, ask your baby's doctor about Enfamil® Enspire™

INSTRUCTIONS FOR PREPARATION & USE

Your baby's health depends on carefully following the instructions below. Proper hygiene, preparation, dilution, use and storage are important when preparing infant formula. Powdered infant formulas are not sterile and should not be fed to premature infants or infants who might have immune problems unless directed and supervised by your baby's doctor. Ask your baby's doctor which formula is appropriate for your baby. Ask your baby's doctor about the need to use cooled, boiled water for mixing and the need to boil clean utensils, bottles and nipples in water before use.

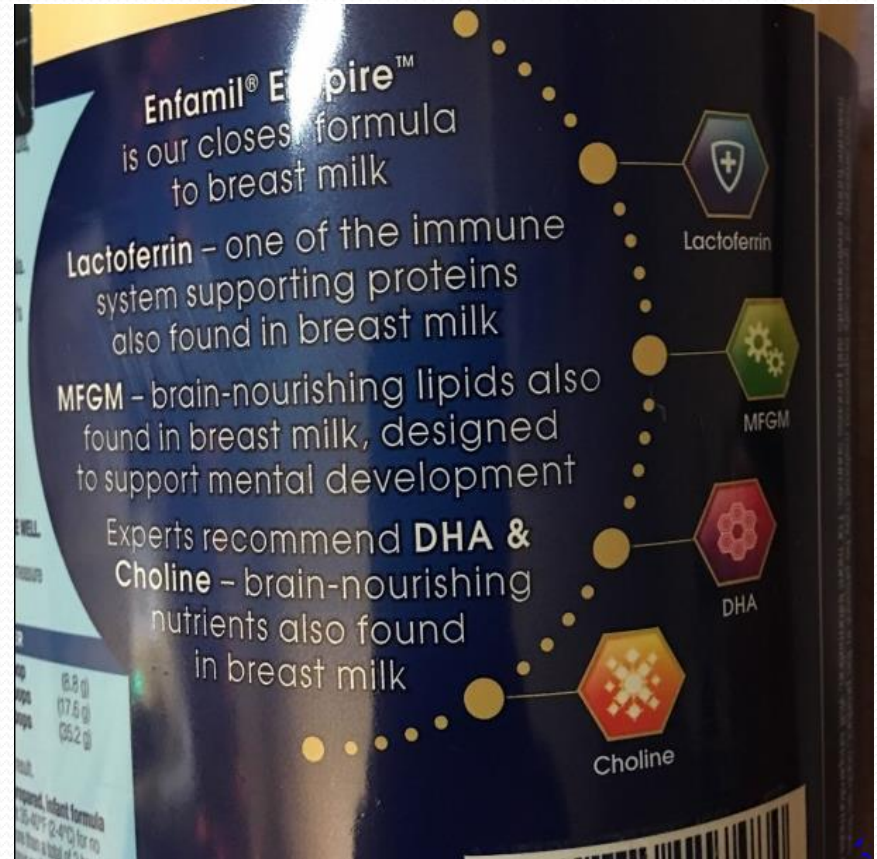
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Wash hands thoroughly with soap & water before preparing formula. Pour desired amount of water into the bottle. Add powder. Cap bottle and **SHAKE WELL**.

Use the chart below for correct amounts of water and powder. Use scoop in tub to measure powder. Store **DRY** scoop in lid holder.

TO MAKE*	WATER	POWDER
2 fl oz bottle	2 fl oz	1 unpacked level scoop (8.8 g)
4 fl oz bottle	4 fl oz	2 unpacked level scoops (17.6 g)
8 fl oz bottle	8 fl oz	4 unpacked level scoops (35.2 g)

*Each scoop adds about 0.2 fl oz to the amount of prepared formula.
WARNING: Do not use a microwave oven to warm formula. Serious burns may result.
Failure to follow these instructions could result in severe harm. Once prepared, infant formula can spoil quickly. Either feed immediately or cover and store in refrigerator at 35-40°F (2-4°C) for no longer than 24 hours. Do not use prepared formula if it is unrefrigerated for more than a total of 2 hours. Do not freeze prepared formula. After feeding begins, use formula within one hour or discard.
Storage/Handling: Store powder at room temperature; avoid extreme temperatures. After opening, keep lid tightly closed, store in a dry area, and use contents within 1 month. Use tub with Enfamil Enspire formula only. Keep powder fresh and prevent bacterial growth by assuring tub is clean and completely dry. Completely empty tub and wipe clean with a clean, dry cloth before refilling.
If you choose to empty pouch into tub, you must retain the batch code and "use by" date sticker from pouch.



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Breast Pumps

- Breast pumps are not a product covered within the scope of the Code
- Collection and storage containers are not products covered under the scope of the Code

What are Code Violations?

- free samples and supplies
- free formula to hospitals, pediatric offices, mailed to mothers through formula clubs, starter packs, discharge gifts
- formula contracts that bind hospitals to give out formula discharge packs



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Hospital enticements

- Mead Johnson purchased 500 licenses for this product and offered them for free to hospitals if they would NOT become Baby Friendly

Welcome to The



Comprehensive, fully-integrated tracking and inventory management system for infant feeding in the hospital

Brought to you by



Important Market Firsts

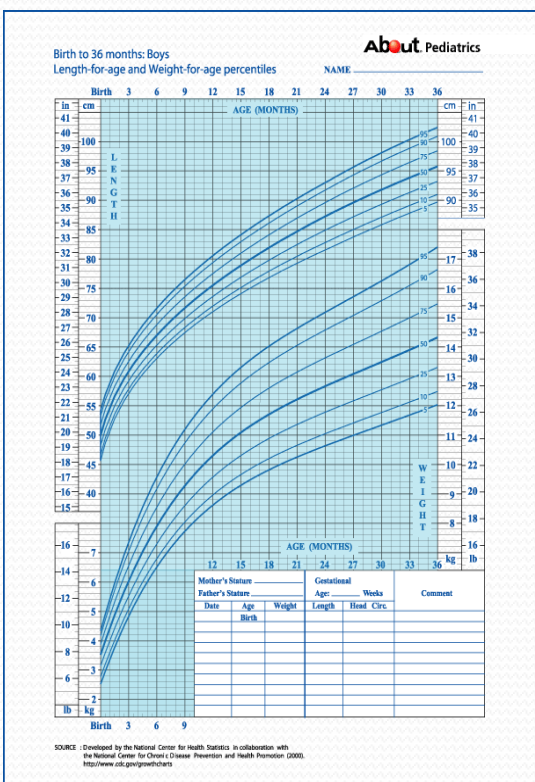
- 1st comprehensive breast milk tracking system
- 1st to market infant formula tracking system
- 1st integrated bar code labeling system



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Posters, Calendars, Displays

- Code articles 6.2, 6.3, 4.3
 - posters, calendars, clocks, stickers, weight charts, teaching flip charts, measuring tapes



Congratulations!

My Name _____ Medical Record # _____

Sex _____ My Birthdate _____ Time _____ Rm _____

Birth Weight _____ lbs. oz. Length _____ in. Head _____ Chest _____

Mother's Doctor _____

My Doctor _____

Congratulations!

My Name _____ Room _____

Sex _____ My Birthdate _____ Time _____

Birth Weight _____ lbs. oz. Length _____ in. Head _____ Chest _____

Mother's Doctor _____

My Doctor _____

Formulas® call toll free: _____
 _____-Friday and 8:00 am- _____
www.family.com

Mead Johnson
Nutritionals

35

**Baby's Own
Tape Measure**



Gifts to Health Workers

- Code Articles 7.3, 6.3, 6.2
- using gifts as inducements to promote products
 - one year free formula to nurses and physicians, trinkets like pens, mugs, note pads, growth charts
 - bigger trinkets like Club Med membership, ski trips, tickets to sporting events, food, cash to hospitals, continuing education programs



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Samples and Gifts to Mothers

- Code Articles 5.2, 5.4
- discharge packs, starter packs, literature, videos, coupons, clubs, contests, logo laden baby products such as bibs, diaper bags, toys



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Sponsorship

- Resolution 49.15
 - acceptance of inappropriate funding may influence the objectivity of training in infant and child health
 - assure that financial support for professionals does not create conflicts of interest
 - financial assistance from the infant feeding industry may interfere with professional's unequivocal support of breastfeeding

Feeding Bottles and artificial nipples

- Code Articles 2,4,5,6,7,9 promotion to the general public
- idealizes bottle-feeding
- markets the concept of equivalency



Introducing Calma: Designed exclusively for breastmilk feeding.

Switching from bottle back to breast has never been easier. Calma was developed using evidence-based research on babies' natural feeding behavior so you can enjoy your breastfeeding bond longer.

With Calma, the milk will only flow if your baby works and creates vacuum to remove the milk. This enables the feeding behavior learned at the breast to be used with Calma.

Bottle feeding



ACCEPTANCE PROVEN!



Our new Natural bottle: The most natural way to bottle feed

[Click on the video above to find out more](#)

Natural bottle range

The Natural bottle is our most innovative and advanced bottle, helping to make bottle feeding more natural for your baby and you. The bottle is perfect for moms who plan on breastfeeding, as baby can now easily combine breast and bottle feeding. Your baby can benefit from your breast milk no matter if you are around or not.

Babies accept our Natural nipple easily*

Research shows that 8 out of 10 babies accept the Natural nipple easily when introduced to our Natural bottle. The wide, breast-shaped nipple has been designed to help your baby latch on naturally. Inside the nipple, special comfort 'petals' increase softness and flexibility – it won't collapse, no matter how enthusiastically your baby is feeding.

With a breast shaped nipple for natural latch on, unique comfort petals and an innovative anti-colic system, it's our most natural bottle yet!

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Favored by moms and dads because they reduce feeding problems like colic, spit-up, burping, and gas. The **Patented Internal Vent System** eliminates air and vacuum to allow baby to feed comfortably. It also reduces air bubble oxidation of the milk to help preserve vitamins and lipids, key nutrients to baby's health.

The fully-vented bottle design provides vacuum-free feeding, like breastfeeding, which can also help reduce build-up of fluid in baby's ear.



With natural colors, textures and forms, the mimijumi baby bottle provides the perfect complement to breastfeeding and the best possible transition to bottle feeding.

The innovative nipple design replicates a mother's breast, creating a natural feeding and latching experience for a happier and healthier bottle fed baby. Bold colors and soft textures are combined to give the mimijumi baby bottle a distinctive, eye-catching appearance.



Offer your baby a seamless transition to bottle feeding with the Babies R Us Purely Simple 5 oz. Wide-Neck Bottle. The soft, slow-flow silicone nipple simulates mom's natural shape and helps make it easy to combine breast and bottle feeding, and it has anti-colic Vent-Tec valves to provide a steady flow of milk to help reduce air-swallowing and post-feeding discomfort. Quick-read gradation lines help you to monitor your baby's intake at a glance, and the tapered shape offers comfort during use and helps make it easy for babies to eventually hold the bottle on their own. The bottle and nipple are BPA free, suitable for sterilization and top-rack dishwasher safe.

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Home / Why Calma?

Why Calma?



Calma was developed using evidence-based research on babies' natural feeding behavior, so you can enjoy your breastfeeding bond longer.

Your baby has a unique sucking pattern, including pauses to swallow and breathe. **By using Calma, your baby is able to feed and pause naturally.** This helps to slow down the feed and results in a calm and relaxed baby during and after feeding. This natural feeding behavior supports easy transition from bottle back to breast.

With Calma, switching from bottle back to breast has never been easier.

Here's how Calma works:

- The flow control valve allows your baby to control milk flow.
- Milk only flows when your baby creates a vacuum.
- Mimics natural feeding behavior: your baby can feed, pause and breathe, similar to breastfeeding.



Natural feeding behavior supports easy transition from bottle to breast.



Calma doesn't leak. Vented nipple designed to help avoid gassiness.



One size/shape nipple for all stages of breastmilk feeding.

“Mimics natural feeding behavior”

“Breastfeeding must be well established before introducing Calma”

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Marketing through sampling

- Old and **effective** marketing tactic
- Likelihood of consumers purchasing product following receipt of free sample is 20%-90%
- Creates brand loyalty and positive brand image
- Samples sent directly to mothers' homes



Benjamin Babbitt--mid 1800s soap manufacturer engages in sampling

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Formula discharge bag is product sampling, not gift-giving

- Hospitals have been giving out formula samples since the 1930s
- Viewed as an endorsement from the healthcare provider rather than an advertisement
- Defined by HIPAA as a form of marketing
- Creates a market where none existed before



Creating a salesforce in disguise

- Sponsorship, funding, supplies, services to hospitals and healthcare providers influence medical care patterns
- Results in distortion, accuracy, completeness & balance of information presented to mothers



Formula Company's View of Nurses

- An old Ross employee manual states, ... “Never underestimate the role of nurses. If they are sold and serviced properly, they can be strong allies. A nurse who supports Ross is like another salesman.”

Outcome of gifting

- Since clinical judgments can be biased by small gifts, recruiting physicians and nurses to distribute formula gifts to new mothers could conflict with a provider's ethical duty to the patient as well as the discipline's scope of practice
- Education offerings, pens, mugs and trinkets given to healthcare providers undermine professional objectivity
- Designed to cause hospitals and healthcare workers to look kindly upon infant formula products and disrupt the unconditional support of breastfeeding

J Hum Lact. 2014 Feb;30(1):73-9.

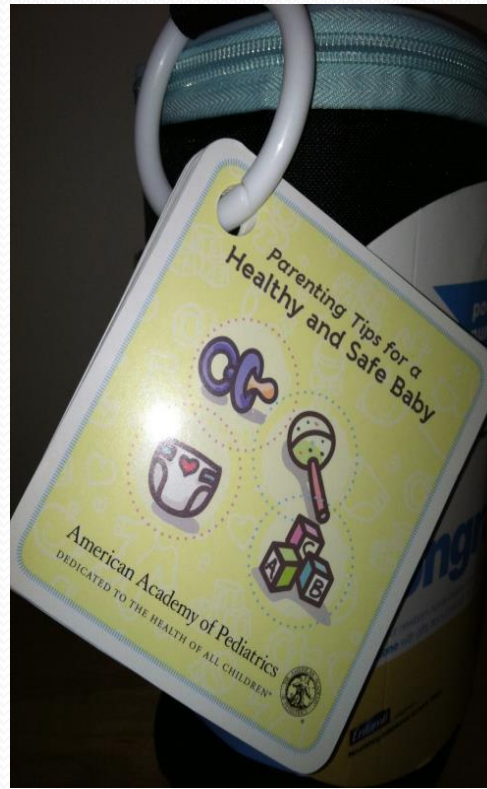
Hospital discharge bags and breastfeeding at 6 months: data from the infant feeding practices study II.

Sadacharan R¹, Grossman X, Matlak S, Merewood A.

- The vast majority of new mothers received formula sample packs at discharge, and this was associated with reduced exclusive breastfeeding at 10 weeks and 6 months.
- Bags containing breastfeeding supplies or no bag at all were positively associated with exclusive breastfeeding at 10 weeks and 6 months

American Academy
of Pediatrics
promotion of
formula

Advocates for breastfeeding but
promotes formula by
distributing commercial bags
causing confusion in mothers



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Gifts have strings attached

- Distorts informed consent
- Prioritizes financial issues above patient care
- Challenges ethics of where professional duties lie
- Exploits patients' fears of inadequacy
- Implies medical endorsement of formula
- Hospitals as a marketing arm for formula companies



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The Code is part of the foundation of BFHI

- **GUIDELINE:** The facility will demonstrate its compliance with the International Code of Marketing of Breast-milk Substitutes by
 - refusing to accept supplies of breast milk substitutes and feeding supplies at no cost or below fair market cost
 - protecting new parents from influence of vendors of such items
 - practicing in accordance with its vendor/ethics policy regarding appropriate interaction between vendors of such items and facility staff
 - educating staff members about the Code and its role in ethical health care practices.

Why?

- Acceptance of funding or other incentives creates a sense of obligation and loyalty to the company in question.
- Invokes the concept of reciprocity
- Have a moral obligation to protect patients from inappropriate promotion of BMS and from resulting competing interests in healthcare settings.
- Hospitals have a moral obligation to respect and protect women's and children's rights to be free from all forms of inappropriate marketing practices.

Why purchase formula?

- Maternity unit is only unit in hospital that receives free food for its patients
- Food is part of the room and board charge
- Free formula has only one reason—to market that brand to new mothers
- Nurses' job description does not include marketing pricey products to vulnerable patients
- Formula manufacturers know that the brand of formula mothers are given in the hospital is the one they are most likely to continue to use through the first year or longer.
- The distribution of materials such as free samples, pamphlets, notepads, growth charts, or gifts that bear logos from companies marketing infant formula implicitly endorses formula feeding

Remove formula marketing from your health care setting

- Eliminate formula company discharge bags from maternity units
- Ask physicians to avoid giving out formula company materials in their offices
- Remove all formula materials from clinics
- Ask ultrasound offices to avoid distributing formula company gifts
- Avoid handing out formula company educational materials
- Do not attend educational offerings sponsored by formula companies
- Do not accept gifts from formula salespeople
- Have a contest to see how many formula company items are present in your facility

Avoid distributing materials from Code violating companies



Going Back to Work

Tips for Continued Successful Breastfeeding



The American Academy of Pediatrics recommends exclusive breastfeeding for the first six months. Women everywhere are returning to work and successfully continuing to breastfeed. Advanced planning, family and workplace support, and a high quality breastpump help create success for working moms. The longer babies are breastfed, the greater the health benefits for both mom and baby. Breastfeeding is good for your employer too – it reduces employees' absence from work for baby's illnesses.



Breastfeed often in the evenings and learn how to breastfeed lying down while you rest. Nighttime breastfeeding boosts your supply! Remember, pumping takes practice. If you only get a small amount of milk the first few times you pump, don't worry. With practice and patience you'll soon be pumping more milk.

Choosing the Right Pump & Accessories

It is important to select the best breastpump and accessories for your work situation. Many working moms choose Freestyle®, Pump in Style® Advanced or a hospital-grade breastpump, such as Symphony®. These pumps offer superior performance, comfort and convenience. Medela pumps have either a vehicle lighter or battery pack for options. Call 1-800 TELL YOU for a local retail or rental location or visit www.medela.com.



Freestyle

Choosing the correct size breastshield is important for the flow of breastmilk and comfort to moms who are pumping. Medela makes PersonalFit™ breastshields in a variety of sizes to fit your needs. Breastpumping should be comfortable. If pumping is uncomfortable or if you have questions, check with your lactation consultant or healthcare professional to help provide you with the proper fit.

Choosing a Childcare Provider for Your Baby

Choose a childcare provider you trust who is comfortable caring for your breastfed baby. You can also check with your state or county for a list of licensed childcare providers. By choosing a childcare provider that is close to your workplace, you can visit your baby and breastfeed during lunch.

Benefits of Breastfeeding

For Baby	For Mom
Breastfed infants have fewer and shorter episodes of illness.	Convenient and always ready for baby.
Nutrition provided by breastmilk benefits your baby's IQ.	Decreases risk of breast and ovarian cancers.
Reduces the risk of obesity and hypertension.	Just the right temperature, and is the healthiest choice at the least cost.
Helps the baby's immune system mature.	Increases the rate of weight loss in most mothers.
Increases the effectiveness of immunizations.	Breastfed babies are healthier, and mothers miss less work and spend less time and money on pediatric care.
Perfect nutrition.	Reduces risk of diabetes, heart attack, high blood pressure and stroke.
Fewer allergies.	Decreases risk of osteoporosis.
Protects against developing chronic diseases.	

...there are many other benefits to breastfeeding. Go to www.medela.com to see references and find more.

You and Your Milk Supply

Your milk supply is established in the first days after birth. Breastfeed your baby frequently to help produce lots of milk. Make use of the time after your baby is born to rest and regain your energy. Avoid giving bottles and/or pacifiers until breastfeeding is well-established.

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Rewards companies for poor corporate behavior



All in all, a new mom's body is pretty amazing. You build this little life inside you, developing it from a tiny bunch of cells into a fully formed baby. Then you give birth to that fully formed baby (and it's worth it!).

Then, that amazing body of yours knows just how to make the perfect food – breastmilk – for nurturing the new love in your life.

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¹ Medela consumer segmentation study, 2008

² American Academy of Pediatrics Policy Statement, Breastfeeding and the Use of Human Milk; Pediatrics, Vol. 115, No. 2, February 2005

³ www.cdc.gov/breastfeeding/faq/; Centers for Disease Control and Prevention; Breastfeeding: Frequently Asked Questions

All research, unless otherwise indicated, was conducted by Dr. Peter Hartmann and his team at the University of Western Australia, Perth and sponsored by Medela, Inc.

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Did you know?

Interesting facts & fun trivia about breastfeeding and breastpumping.

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The free stuff is not free

- Who pays for the free stuff?
- **MOTHERS PAY FOR THE “FREE” STUFF**
- Mothers are targeted and marketed to heavily throughout pregnancy, in the hospital, and through the first year and beyond
- Marketing efforts drive up the cost of formula
- Many mothers cannot afford to pay for dinners for physicians and nurses
- **Q: What will Enspire cost?**
A: While prices are at the sole discretion of retailers, Enspire will have a suggested retail price of \$39.99, which is approximately 50% more than Enfamil Infant and Gentlease.
- The expense of the ingredients (due to their scarcity and the expertise needed to extract them from dairy sources) is driving the cost.
- Milk fat globule membrane



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Anticipating Resistance

- Anti-business
- Anti-choice
- Government regs are intrusive & unnecessary
- Makes women feel guilty
- Deprives poor women of gifts/elitist
- Formula is safe and healthy/millions raised on it with no problems



Anticipating resistance

- We need to give out these bags
- Bag removal interferes with doctor/patient relationship
- The Code is outdated
- The Code is only for developing countries
- I am not influenced by advertising



Well then, what can we give out?

- Non-proprietary materials
- Make your own discharge bag
- Pump kits
- Instructions for the use of a pump
- Coupons and products from Code compliant companies
- Contact information for community breastfeeding support
- Some hospitals do not give out any gifts
- Be creative



Make Your Own Bag



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