

Complaint

IN THE MATTER OF

**CLEAR CHOICE HOUSEWARES, INC. D/B/A
FARBERWARE® ECOFRESH**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATION OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket No. C-4420; File No. 122 3288**Complaint, December 11, 2013 – Decision, December 11, 2013*

This consent order addresses allegations that Clear Choice Housewares, Inc., doing business as Farberware EcoFresh, made false and misleading claims concerning the biodegradability of its reusable plastic food storage containers. According to the complaint, respondent represented that its plastic products were completely biodegradable and would completely break down and decompose into elements found in nature within a reasonably short time period after customary disposal. The complaint alleges that each of its degradable claims were false and misleading and that respondent did not possess any substantiation for its claims. The order bars respondent from representing any of its products or packaging are biodegradable unless (1) the entire item will completely decompose into elements found in nature within one year after disposal; or (2) respondent clearly and prominently states the time to complete decomposition or explains the extent to which the item will decompose. The order further requires respondent to implement scientific protocols that replicates the physical conditions found in a landfill or existing using the method or facility stated in respondent's representations regarding its product's biodegradability. Additionally, the order requires respondent to submit an initial compliance report to the Commission and make subsequent reports available to the Commission.

Participants

For the *Commission*: *Korin Felix, Elisa Jillson, and Katherine Johnson.*

For the *Respondent*: *Not represented by counsel.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Clear Choice Housewares, Inc., also d/b/a FARBERWARE® EcoFresh ("respondent"), has violated provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

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1. Respondent Clear Choice Housewares, Inc., also d/b/a FARBERWARE® EcoFresh, is a Massachusetts corporation with its registered place of business at 163 Pioneer Drive Suite 201, Leominster, MA 01453.

2. Respondent advertises, offers for sale, sells and distributes food storage containers, including “FARBERWARE® EcoFresh Containers,” to the public throughout the United States. Respondent advertises these goods through the Internet site www.farberwarefoodstorage.com. Respondent also offers for sale, sells, and distributes these goods through various online and brick-and-mortar retail locations throughout the United States. Respondent advertises that FARBERWARE® EcoFresh Containers are biodegradable because of an additive known as EcoPure.

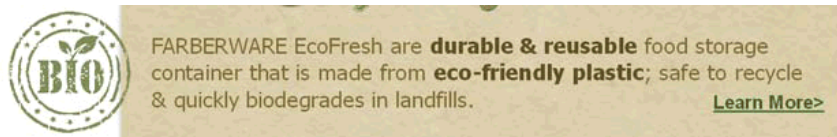
3. The acts and practices of respondent alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

4. To induce consumers to purchase FARBERWARE® EcoFresh Containers, respondent disseminates, has disseminated, or has caused to be disseminated advertisements and promotional materials, including, but not limited to, those attached in Exhibit 1.

5. In its advertising and promotional materials, including, but not limited to, those shown in Exhibit 1, respondent has made the following statements and depictions:

Respondent’s Website (Exhibit 1):

i. Homepage:



(Ex. 1, at 1).

ii. FAQs Page:

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“What makes your products biodegrade? EcoPure, a patented blend of organic ingredients, is the catalyst that promotes microbial activity to devour and biodegrade the plastic.” (Id., at 2).

iii. EcoPure® Page:

1. “FARBERWARE® EcoFresh has the exclusive rights to a revolutionary biodegradable additive, EcoPure, making our containers the first ever biodegradable, recyclable & reusable food storage container system in the world.” (Id., at 3).

2. “EcoPure® is a second generation additive, which once added to a resin type during the manufacturing process, renders plastics biodegradable.” (Id.).

3. “Various ASTM (American Society for Testing and Materials) testing methods have proven that EcoPure is biodegradable, including the ASTM D5511-02, which confirms that products will biodegrade when placed into an aerobic or anaerobic environment, such as a landfill.” (Ex. 1, at 3).

4. “EcoPure only begins biodegrading once it is in a landfill environment, and takes approximately 2-10 years to fully biodegrade, depending on gram weight and microbial enrichment in the landfill. Tests have shown that as little as 1% (by gram weight) of EcoPure is needed to make a product biodegradable.” (Id.).

iv. Products Pages:

Each FARBERWARE® EcoFresh Container is described as “biodegradable.” (Id., at 4-8).

6. Approximately 92 percent of total municipal solid waste in the United States is disposed of either in landfills, incinerators, or recycling facilities. These disposal methods do not present conditions that would allow respondent’s FARBERWARE®

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EcoFresh Containers to completely break down and decompose into elements found in nature within a reasonably short period of time.

7. Consumers likely interpret unqualified degradable claims to mean that the entire product or package will completely decompose into elements found in nature within a reasonably short period of time after customary disposal.

8. American Society for Testing and Materials (“ASTM”) International D5511, Standard Test Method for Determining Anaerobic Biodegradation of Plastic Materials under High Solids Anaerobic Digestion Conditions (“ASTM D5511”), and other scientific tests relied on by respondent do not assure complete decomposition of FARBERWARE® EcoFresh Containers in a reasonably short period of time or in respondent’s stated timeframes, e.g., 2-10 years, and do not replicate, i.e., simulate, the physical conditions of either landfills, where most trash is disposed, or other disposal facilities stated in the representations.

VIOLATIONS OF SECTION 5 OF THE FTC ACT**FALSE OR MISLEADING REPRESENTATIONS**

9. Through the means described in Paragraphs 2, 4, and 5, respondent has represented, expressly or by implication, that:

- A. FARBERWARE® EcoFresh Containers are biodegradable, i.e., will completely break down and decompose into elements found in nature within a reasonably short period of time after customary disposal;
- B. FARBERWARE® EcoFresh Containers are biodegradable in a landfill;
- C. FARBERWARE® EcoFresh Containers are biodegradable in a stated qualified timeframe;
- D. FARBERWARE® EcoFresh Containers are biodegradable, biodegradable in a landfill, or

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biodegradable in a stated qualified timeframe as a result of an additive known as EcoPure; and

- E. FARBERWARE® EcoFresh Containers have been shown to be biodegradable, biodegradable in a landfill, or biodegradable in a stated qualified timeframe under various scientific tests including, but not limited to, ASTM D5511.

10. In truth and in fact:

- A. FARBERWARE® EcoFresh Containers will not completely break down and decompose into elements found in nature within a reasonably short period of time after customary disposal;
- B. FARBERWARE® EcoFresh Containers will not completely break down and decompose into elements found in nature within a reasonably short period of time after disposal in a landfill;
- C. FARBERWARE® EcoFresh Containers will not completely break down and decompose into elements found in nature within respondent's stated qualified timeframes after customary disposal;
- D. FARBERWARE® EcoFresh Containers will not completely break down and decompose into elements found in nature within a reasonably short period of time after customary disposal, after disposal in a landfill, or within respondent's stated qualified timeframe as a result of respondent's use of an additive known as EcoPure; and
- E. FARBERWARE® EcoFresh Containers have not been shown to completely break down and decompose into elements found in nature within a reasonably short period of time after customary disposal, after disposal in a landfill, or within respondent's stated qualified timeframe, under various scientific tests, including, but not limited to, ASTM D5511.

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11. Therefore, the representations set forth in Paragraph 9 were, and are, false or misleading.

UNSUBSTANTIATED REPRESENTATIONS

12. Through the means described in Paragraphs 2, 4, and 5, in numerous instances respondent has represented, expressly or by implication, that it possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 9, at the time the representations were made.

13. In truth and in fact, at the time respondent made the representations referred to in Paragraph 9, respondent did not possess and rely upon a reasonable basis that substantiated such representations. Therefore, the representation set forth in Paragraph 12 is false or misleading.

14. Respondent's practices, as alleged in this complaint, therefore, constitute deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act.

IN WITNESS WHEREOF, the Federal Trade Commission has issued this complaint against respondent and has caused it to be signed by its Secretary and its official seal to be hereto affixed, at Washington, D.C. this eleventh day of December, 2013.

By the Commission.

Complaint

EXHIBIT 1

CHAMP | Zarma FLYtee™ Combi-Pak

Home

CHAMP The World Leader in Sport Cleat Technology®

NEWS & EVENTS PRODUCT INFORMATION WHY CHAMP SPIKES? WHERE TO BUY

FLYtees™ Golf Football Soccer Track Baseball Rugby Lacrosse Cricket

FLYtees™ Industrial

- Zarma FLYtee™ MySite™ Tee
- Zarma FLYtee™ 3 1/2"
- Zarma FLYtee™ 2 1/2"
- Zarma FLYtee™ 1 1/2"
- Zarma FLYtee™ Combi-Pak
- Zarma FLYtee™ Multi-Color Pack 2 1/2"
- Custom Printed FLYtees
- ZARMA FLYtee™ Biodegradability Information

CHAMP Tee-It-Up™

Wrenches

Divot Tools

Other Accessories

Ball Markers



Zarma FLYtee™ Combi-Pak
CHAMP GOLF ACCESSORIES
White/Orange Combination Pak

Buy Now

- Overview
- Specifications
- Part Numbers

Finally a performance Tee that Performs!

The CHAMP Zarma FLYtee™ is a new performance tee that will increase your distance and accuracy from tee to green. Made with environmentally friendly biodegradable materials, a durable plastic design and a 6 prong head makes it easier to place the ball on the tee and keep it stable. With its added durability and contoured cup, this tee gives top performance to all golfers, from amateurs to professionals.

Specifications

A combination pack of 15 white 2 1/2" (63mm) length tees and 8 orange 1 1/2" (44mm) length tees. Package contains 23 tees.

Product not available in the US.

Download Sell Sheet

Download High Res Product Images

Part Numbers

Pack of 23
Combi-Pak No.90561

White 2 1/2" (15)
Orange 1 1/2" (8)

Product not Available in the US

http://www.champspikes.com/products/golf/accessories/ly-tees/zarma-flytee-combi-pak/[8/10/2012 9:43:46 AM]

CHAMP | Zarma FLYtee™ Combi-Pak

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EXHIBIT 1

CHAMP | ZARMA FLYtee™ Biodegradability Information

CHAMP The World Leader in Sport Cleat Technology®

Distributions Retailers OEM Contact 1.800.OK.CHAMP

NEWS & EVENTS PRODUCT INFORMATION WHY CHAMP SPIKES? WHERE TO BUY

Golf Football CORPUSCULE INFORMATION Track Baseball Rugby Lacrosse Cricket

Industrial

Home / Products / Golf / Golf Accessories / FLYtees™ / ZARMA FLYtee™ Biodegradability Information

FLYtees™

Zarma FLYtee™ MyHite™ Tee
Zarma FLYtee™ 3 1/2"
Zarma FLYtee™ 2 3/4"
Zarma FLYtee™ 1 3/4"
Zarma FLYtee™ Combi-Pak
Zarma FLYtee™ Multi-Color Pack 2 3/4"
Custom Printed FLYtees
ZARMA FLYtee™ Biodegradability Information

CHAMP Tee-it-Up™
Wrenches
Divot Tools
Other Accessories
Ball Markers



ZARMA FLYtee™ Biodegradability Information
CHAMP GOLF ACCESSORIES

FLYtees are completely biodegradable!

Overview
Specifications
Part Numbers

FLYtees are completely biodegradable!

The CHAMP FLYtee is from a specially formulated sustainable bio-plastic that enables the material to maintain durability and performance, while still breaking down into CO2 and water when it is done being used. Our plastic has a market proven bio-agent additive created by ECM Bioline, Inc. ECM's technology is a process which enables the microorganisms in the environment to metabolize the molecular structure of plastic products into humus that is beneficial to the environment.

Specifications

- Download Sell Sheet
- Download Technical Sheet

Part Numbers

Reduce...Reuse...Recycle

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EXHIBIT 1



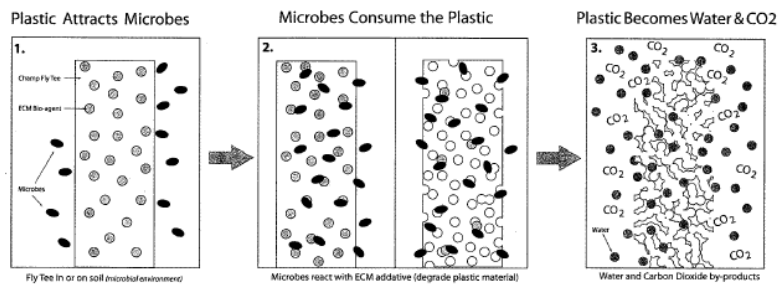
Sustainable Design



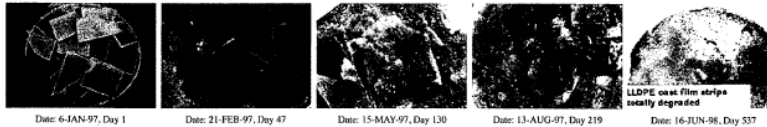
The Champ Fly Tee is made from a specially formulated sustainable bioplastic that enables the material to maintain durability and performance, while still breaking down into CO₂ and Water when it is done being used. Our plastic has a market proven bio-agent additive created by ECM Biofilms, Inc. ECM's technology is a process which enables the microorganisms in the environment to metabolize the molecular structure of plastic products into humus that is beneficial to the environment.



Degradation Illustration



Actual Test Performed by ECM



Actual tee degradation times will vary depending upon the location of the tee and its surrounding environment.

www.ecmbiofilms.com

Material treated with ECM has been tested and proved as biodegradable and safe for the environment by using the following:

ASTM D5209

"Standard Test Method for Determining the Aerobic Biodegradation of Plastic Materials in the Presence of Municipal Sewage Sludge"

ASTM 5511

"Standard Test Method for Determining Anaerobic Biodegradation of Plastic Materials Under High-Solids Anaerobic Digestion Conditions"

ISO 14855 / ASTM D5338

"Standard Test Method for Determining Aerobic Biodegradation of Plastic Materials under Controlled Composting Conditions"

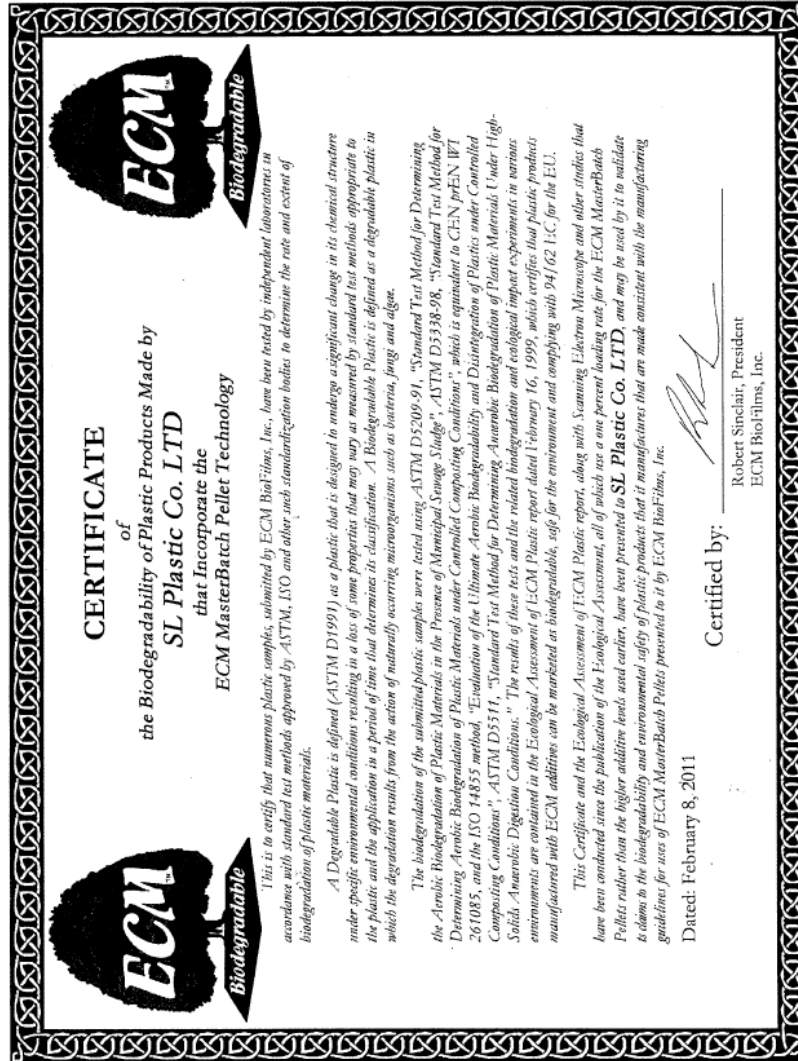
www.champgolf.com

CHAMP

800.OK.CHAMP

Complaint

EXHIBIT 1



Complaint

EXHIBIT 2



Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft complaint that the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge the respondent with violation of the Federal Trade Commission Act, 15 U.S.C § 45 *et seq.*; and

The respondent and counsel for the Commission having thereafter executed an agreement containing a consent order (“consent agreement”), a statement that respondent neither admits nor denies any of the allegations in the draft complaint except as specifically stated in the consent agreement, an admission by the respondent of facts necessary to establish jurisdiction for purposes of this action , and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it has reason to believe that the respondent has violated the Federal Trade Commission Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such consent agreement on the public record for a period of thirty (30) days, and having duly considered the comments filed thereafter by interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34, now in further conformity with the procedure prescribed in Commission Rule 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

- 1 Respondent Clear Choice Housewares, Inc. is a Massachusetts corporation with its registered place of business at 163 Pioneer Drive Suite 201, Leominster, Massachusetts 01453.
2. The Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

Decision and Order

ORDER**DEFINITIONS**

For purposes of this order, the following definitions shall apply:

- 1 “Clearly and Prominently” means as follows:
 - A. In print communications, the disclosure shall be presented in a manner that stands out from the accompanying text, so that it is sufficiently prominent, because of its type size, contrast, location, or other characteristics, for an ordinary consumer to notice, read and comprehend it;
 - B. In communications made through an electronic medium (such as television, video, radio, and interactive media such as the Internet, online services, and software), the disclosure shall be presented simultaneously in both the audio and visual portions of the communication. In any communication presented solely through visual or audio means, the disclosure shall be made through the same means through which the communication is presented. In any communication disseminated by means of an interactive electronic medium such as software, the Internet, or online services, the disclosure must be unavoidable. Any audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. Any visual disclosure shall be presented in a manner that stands out in the context in which it is presented, so that it is sufficiently prominent, due to its size and shade, contrast to the background against which it appears, the length of time it appears on the screen, and its location, for an ordinary consumer to notice, read and comprehend it; and

Decision and Order

- C. Regardless of the medium used to disseminate it, the disclosure shall be in understandable language and syntax. Nothing contrary to, inconsistent with, or in mitigation of the disclosure shall be used in any communication.
- 2.. “Close proximity” means on the same print page, web page, online service page, or other electronic page, and proximate to the triggering representation, and not accessed or displayed through hyperlinks, pop-ups, interstitials, or other means.
3. “Commerce” means as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- 4 “Competent and reliable scientific evidence” means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, that are generally accepted in the profession to yield accurate and reliable results, and that are sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that a representation is true. Specifically:
- A. For unqualified biodegradability claims, any scientific technical protocol (or combination of protocols) substantiating such claims must assure complete decomposition within one year and replicate, i.e., simulate, the physical conditions found in landfills, where most trash is disposed.
- B. For qualified biodegradability claims, any scientific technical protocol (or combination of protocols) substantiating such claims must both:
- i. assure the entire product will (1) completely decompose into elements found in nature in the stated timeframe or, if not qualified by time, within one year; or (2) decompose into

Decision and Order

elements found in nature at the rate and to the extent stated in the representation; and

- ii. replicate, i.e., simulate, the physical conditions found in the type of disposal facility or method stated in the representation or, if not qualified by disposal facility or method, the conditions found in landfills, where most trash is disposed.

For example, results from ASTM (American Society for Testing and Materials) International D5511-12, Standard Test Method for Determining Anaerobic Biodegradation of Plastic Materials under High Solids Anaerobic Digestion Conditions, or any prior version thereof, are not competent and reliable scientific evidence supporting unqualified claims, or claims of outcomes beyond the parameters and results of the actual test performed.

- 5 .”Customary disposal” means any disposal method whereby respondent’s products ultimately will be disposed of in a landfill, in an incinerator, or in a recycling facility.
- 6 .”Degradable” includes biodegradable, oxo-biodegradable, oxo-degradable, or photodegradable, or any variation thereof.
- 7 .”Landfill” means a municipal solid waste landfill that receives household waste. “Landfill” does not include landfills that are operated as bioreactors or those that are actively managed to enhance decomposition.
- 8 .Unless otherwise specified, “respondent” means Clear Choice Housewares, Inc., a corporation, and its successors and assigns.

I.

IT IS ORDERED that respondent, and its officers, agents, representatives, and employees, directly or through any

Decision and Order

corporation, partnership, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product, package, or service, in or affecting commerce, shall not represent, in any manner, directly or indirectly, expressly or by implication:

- A. That any product or package is degradable, unless:
1. the entire item will completely decompose into elements found in nature within one year after customary disposal; or
 2. the representation is clearly and prominently and in close proximity qualified by:
 - a. Either (1) the time to complete decomposition into elements found in nature; or (2) the rate and extent of decomposition into elements found in nature, provided that such qualification must disclose that the stated rate and extent of decomposition does not mean that the product or package will continue to decompose; and
 - b. If the product will not decompose in a customary disposal facility or by a customary method of disposal, both (1) the type of non-customary disposal facility or method and (2) the availability of such disposal facility or method to consumers where the product or package is marketed or sold
- and such representation is true, not misleading, and, at the time it is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.
- B. That any such product, package, or service offers any environmental benefit, unless the representation is true, not misleading, and, at the time it is made, respondent possesses and relies upon competent and reliable evidence, which when appropriate must be

Decision and Order

competent and reliable scientific evidence, that substantiates the representation.

II.

IT IS FURTHER ORDERED that respondent shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Commission for inspection and copying:

- A. All advertisements, labeling, packaging and promotional materials containing the representations specified in Part I;
- B. All materials that were relied upon in disseminating the representations specified in Part I;
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in its possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations; and
- D. All acknowledgments of receipt of this order, obtained pursuant to Part III.

III.

IT IS FURTHER ORDERED that respondent shall deliver a copy of this order to all current and future subsidiaries, current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities relating to the subject matter of this order. Respondent shall secure from each such person a signed and dated statement acknowledging receipt of the order, with any electronic signatures complying with the requirements of the E-Sign Act, 15 U.S.C. § 7001 *et seq.* Respondent shall deliver this order to current personnel within thirty (30) days after the date of service

Decision and Order

of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

IV.

IT IS FURTHER ORDERED that respondent shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including, but not limited to, a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor entity; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the business or corporate name or address. *Provided, however,* that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge.

Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to Debrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Mail Stop M-8102B, Washington, DC 20580. The subject line must begin: "Clear Choice Housewares, Inc., File No. 1223288."

V.

IT IS FURTHER ORDERED that respondent shall, within sixty (60) days after the date of service of this order file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form in which respondent has complied with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, respondent shall submit additional true and accurate written reports. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to Debrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer

Decision and Order

Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Mail Stop 8102-B, Washington, DC 20580. The subject line must begin: “Clear Choice Housewares, Inc., File No. 1223288.”

VI.

This order will terminate on December 11, 2033, or twenty (20) years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order’s application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Analysis to Aid Public Comment

**ANALYSIS OF CONSENT ORDER
TO AID PUBLIC COMMENT**

The Federal Trade Commission (“FTC” or “Commission”) has accepted, subject to final approval, an agreement containing a consent order from Clear Choice Housewares d/b/a FARBERWARE® EcoFresh, a corporation (“respondent”).

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement’s proposed order.

This matter involves respondent’s marketing, sale, and distribution of purportedly biodegradable reusable plastic food storage containers to the public. According to the FTC complaint, respondent represented that its plastic products are completely biodegradable (i.e., will completely break down and decompose into elements found in nature within a reasonably short period of time after customary disposal). Respondent further represented that its plastic products are biodegradable in a landfill; are biodegradable in a stated qualified timeframe; and are biodegradable, biodegradable in a landfill, or biodegradable in a stated qualified timeframe as a result of respondent’s use of EcoPure, a plastic additive manufactured by Bio-Tec Environmental, LLC.

The complaint alleges that each of these degradable claims is false and misleading. In addition, the complaint alleges that, although respondent represented (expressly or implicitly) that it could substantiate its degradable claims, respondent did not in fact possess or rely upon a reasonable basis to substantiate these representations of biodegradability. Thus, the complaint alleges that respondent engaged in deceptive practices in violation of Section 5(a) of the FTC Act.

The proposed consent order contains a provision designed to prevent respondent from engaging in similar acts and practices in the future. Part I prohibits respondent from making any

Analysis to Aid Public Comment

representation that a product or package is degradable, unless one of two conditions is met. The first condition is that the entire item will completely decompose into elements found in nature within one year after customary disposal. The second condition is that the representation will be clearly and prominently and in close proximity qualified by either the time to complete decomposition or the rate and extent of decomposition (although this qualification must disclose that the stated rate and extent of decomposition does not mean that the item will continue to decompose). In addition, if the product will not decompose in (or by) a customary disposal facility/method, the representation must be qualified regarding the type of disposal, and the availability of such disposal facility or method to consumers where the item is marketed and sold.

Part I also requires that, at the time of any such representation, respondent must possess and rely upon competent and reliable scientific evidence from a scientific technical protocol (or protocols) that does two things. First, the protocol must assure that the entire product will either completely decompose in one year or the stated timeframe, or that it will decompose at the rate and to the extent stated in the representation. Second, such protocol must replicate (i.e., simulate) the physical conditions found in a landfill or the disposal facility or method stated in the representation. Part I further prohibits respondent from marketing any products, packages, or services as offering any environmental benefit, unless the representation is true, not misleading, and, at the time it is made, respondent possesses and relies upon competent and reliable evidence that substantiates the representation.

Parts II through V are reporting and compliance provisions. Part II requires respondent to keep (and make available to the Commission on request): copies of advertisements, labeling, packaging and promotional materials containing the representations identified in Part I; materials relied upon in disseminating those representations; evidence that contradicts, qualifies, or calls into question the representation, or the basis relied upon for the representation, specified in Part I; and all acknowledgments of receipt of the order. Part III requires dissemination of the order now and in the future to subsidiaries,

Analysis to Aid Public Comment

principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having supervisory responsibilities relating to the subject matter of the order. Part IV requires notification to the FTC of changes in corporate status. Part V mandates that respondent submit an initial compliance report to the FTC and make available to the FTC subsequent reports. Part VI is a provision “sunsetting” the order after twenty (20) years, with certain exceptions.

The purpose of the analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the proposed order or to modify its terms in any way.

Complaint

IN THE MATTER OF

**MYLAN INC., AGILA SPECIALTIES
GLOBAL PTE. LIMITED, AGILA SPECIAL
PRIVATE LIMITED, AND STRIDES ARCOLAB
LIMITED**

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATION OF
SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL TRADE
COMMISSION ACT

Docket No. C-4413; File No. 131 0112

Complaint, September 26, 2013 – Decision, December 12, 2013

This consent order addresses the \$1.85 billion acquisition by Mylan Inc. (“Mylan”) of Agila Specialties Global Pte. Limited (“Agila”) from Strides Arcolab, Ltd. The complaint alleges that the acquisition would violate Section 7 of the Clayton Act by substantially lessening competition in eleven product markets relating to generic injectable pharmaceutical drugs. Injectable drugs are administered intravenously, usually via a syringe or hollow needle. Generic versions of injectable drugs are usually launched after a branded product’s patents have expired. As the number of generic suppliers increases, prices for these generic drugs generally decrease. The complaint alleges that Mylan and Agila are two of a limited number of current or likely future competitors in several markets for generic injectable pharmaceutical drugs. Specifically, the complaint alleges that the acquisition would eliminate existing competition in the market for the following six generic drugs: (1) amiodarone hydrochloride injection, an anti-arrhythmic heart drug used to treat patients with frequently recurring ventricular fibrillation or unstable ventricular tachycardia; (2) etomidate injection, an anesthetic; (3) fluoruracil injection, used to treat cancer; (4) labetalol hydrochloride injection, used to treat hypertension; (5) mesna injection, used to prevent urinary tract damage; and (6) methotrexate sodium, used to treat types of pediatric cancer. The complaint further alleges that the acquisition would reduce future competition by allowing the combined company to forego or delay the launch of generic products in the following four drug markets: (1) acetylcysteine, used to prevent or minimize liver damage caused by acetaminophen overdose; (2) fomepizole, which is used to treat accidental poisoning caused by ethylene glycol or methanol; (3) ganciclovir, an antiviral drug used to treat patients with weakened immune systems to slow the growth of a form of herpes that can lead to blindness; and (4) meropenem, an antibiotic used to treat serious bacterial infections. The complaint further alleges that the acquisition likely would reduce competition in the future market for generic mycophenolate mofetil injection, which is currently available as a branded drug. Mycophenolate mofetil is used in transplant medicine to reduce the chance of organ transplant rejection. Because Mylan and Agila would likely be among a limited number of suppliers when generic drugs enter the market, the acquisition is likely to reduce the number of generic competitors or otherwise reduce important price competition. The consent