



# WEBINAR

Find the Regulatory Documents  
You Need With REX<sup>®</sup>

**Presented by ESHA Research**

Wednesday, January 12, 2022

11:00 AM PT | 1:00 PM CT | 2:00 PM ET



# ESHA Research

ESHA Research was established in 1981 as one of the very first nutrition software solutions. Today, ESHA's suite of nutritional software products, services, and databases are recognized as the industry's top choice for food and supplement formulation, recipe development, labeling, nutritional analysis, and regulatory compliance.

## **ESHA Solutions**

- Genesis R&D® Food Formulation
- Genesis R&D® Supplement Formulation
- REX® Regulations Expert Document Search Portal
- Food Processor® Nutrition & Diet Analysis
- Consulting Services

Our mission is to help remove the complexity of product development and regulatory compliance for the food, beverage, and supplement industries through software, services, and nutritional databases.

# Upcoming Webinars

Stay tuned for the 2022 webinar schedule. We will be introducing new Regulatory Focused webinars!

## ESHA Webinar Notification Signup Page

<https://esha.com/news-events/webinar-notice-signup>


First Name 

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Company 

Job Title 

Email 

- Webinar Topics 
- ☐ Genesis R&D Food Software
  - ☐ Genesis R&D Supplements Software
  - ☐ Food Processor Software
  - ☐ Food Labeling Regulatory Compliance
  - ☐ Supplement Labeling Regulatory Compliance
  - ☐ Menu Labeling Regulatory Compliance

Sign Up

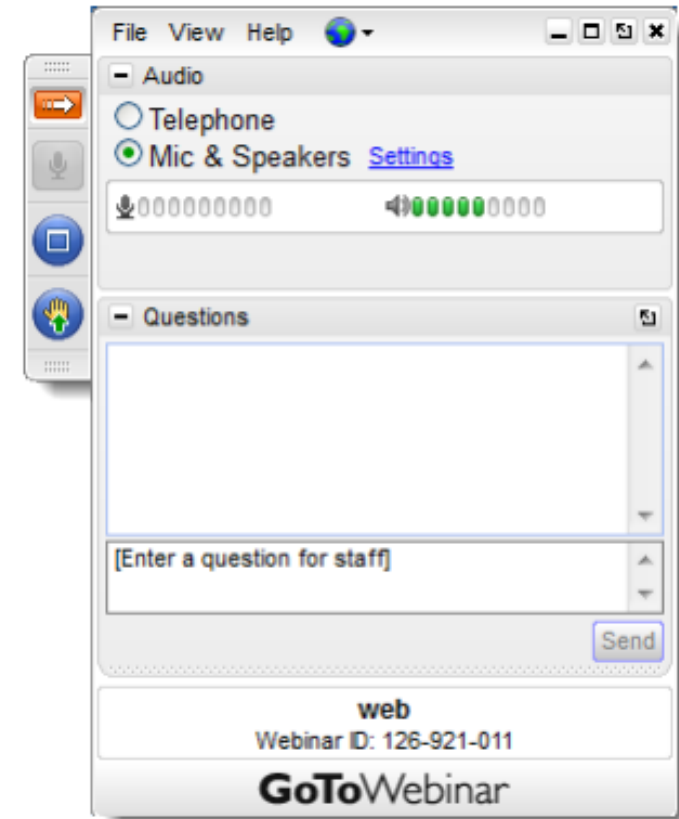
To view archived webinars: [www.esha.com/news-events/webinars](http://www.esha.com/news-events/webinars)





# Please Note!

- ✓ The webinar is being recorded
- ✓ All webinars available on our website
- ✓ Submit your questions in the GoToWebinar control panel
- ✓ We'll email a copy of the recording and the slides following the webinar



# What We'll Cover Today

- REX Overview
- Searching
- Review Search Results
- Viewing Documents
- Bookmarking Favorites
- Q&A





# Introducing: REX<sup>®</sup>

REX is ESHA Research's online documentation portal that provides quick and easy access to regulatory and guidance documentation relevant to the food and supplement manufacturing industries.



## Resources

- FDA final rule and guidance documents
- USDA final rule and guidance documents
- Relevant documents for labeling
- Curated by ESHA

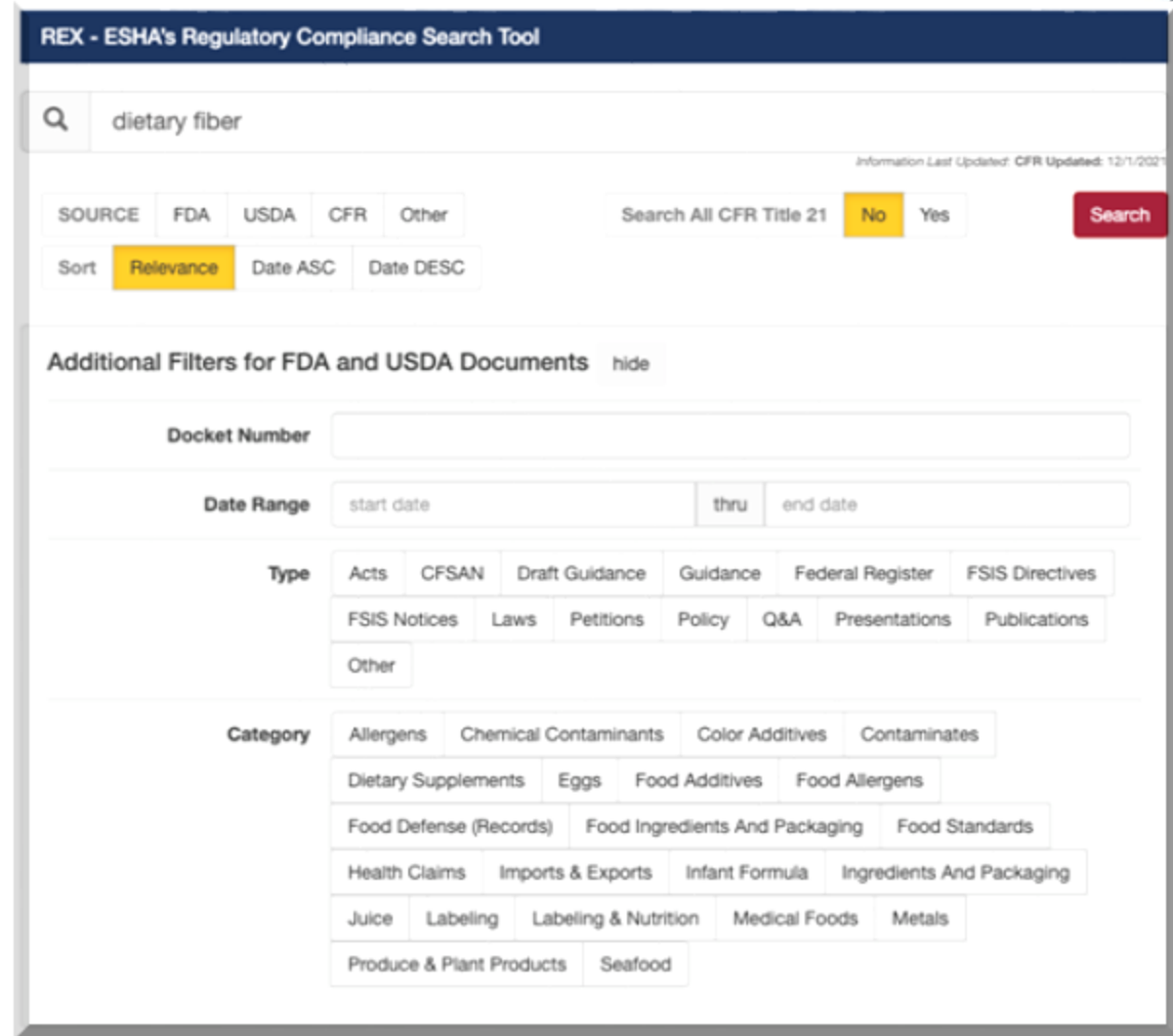


**CODE OF FEDERAL  
REGULATIONS**



# Searching

- Enter full or partial words to the search bar
- Narrow your search by source, date, type, and category
- Sort results by Relevance (default) or by date in ascending (ASC) or descending (DESC) order.



The screenshot displays the REX - ESHA's Regulatory Compliance Search Tool interface. At the top, a dark blue header contains the title "REX - ESHA's Regulatory Compliance Search Tool". Below the header, a search bar with a magnifying glass icon contains the text "dietary fiber". To the right of the search bar, a small text link reads "Information Last Updated: CFR Updated: 12/1/2021".

Below the search bar, there are several filter and sorting options. A row of buttons labeled "SOURCE" includes "FDA", "USDA", "CFR", and "Other". To the right of these buttons is a section for "Search All CFR Title 21" with "No" and "Yes" buttons, and a red "Search" button. Below this, a "Sort" section includes buttons for "Relevance" (highlighted in yellow), "Date ASC", and "Date DESC".

Further down, a section titled "Additional Filters for FDA and USDA Documents" with a "hide" link is visible. It contains several filter categories:

- Docket Number:** A text input field.
- Date Range:** Fields for "start date", "thru", and "end date".
- Type:** A grid of buttons including "Acts", "CFSAN", "Draft Guidance", "Guidance", "Federal Register", "FSIS Directives", "FSIS Notices", "Laws", "Petitions", "Policy", "Q&A", "Presentations", "Publications", and "Other".
- Category:** A grid of buttons including "Allergens", "Chemical Contaminants", "Color Additives", "Contaminates", "Dietary Supplements", "Eggs", "Food Additives", "Food Allergens", "Food Defense (Records)", "Food Ingredients And Packaging", "Food Standards", "Health Claims", "Imports & Exports", "Infant Formula", "Ingredients And Packaging", "Juice", "Labeling", "Labeling & Nutrition", "Medical Foods", "Metals", "Produce & Plant Products", and "Seafood".



# Matching Search Results

View number of match hits from each source:

You Searched For:

**dietary fiber**

Too many results? Show or hide result sources using the buttons below. Toggling sources does not affect results; only display.

☒ CFR - 1 documents - 4 instances

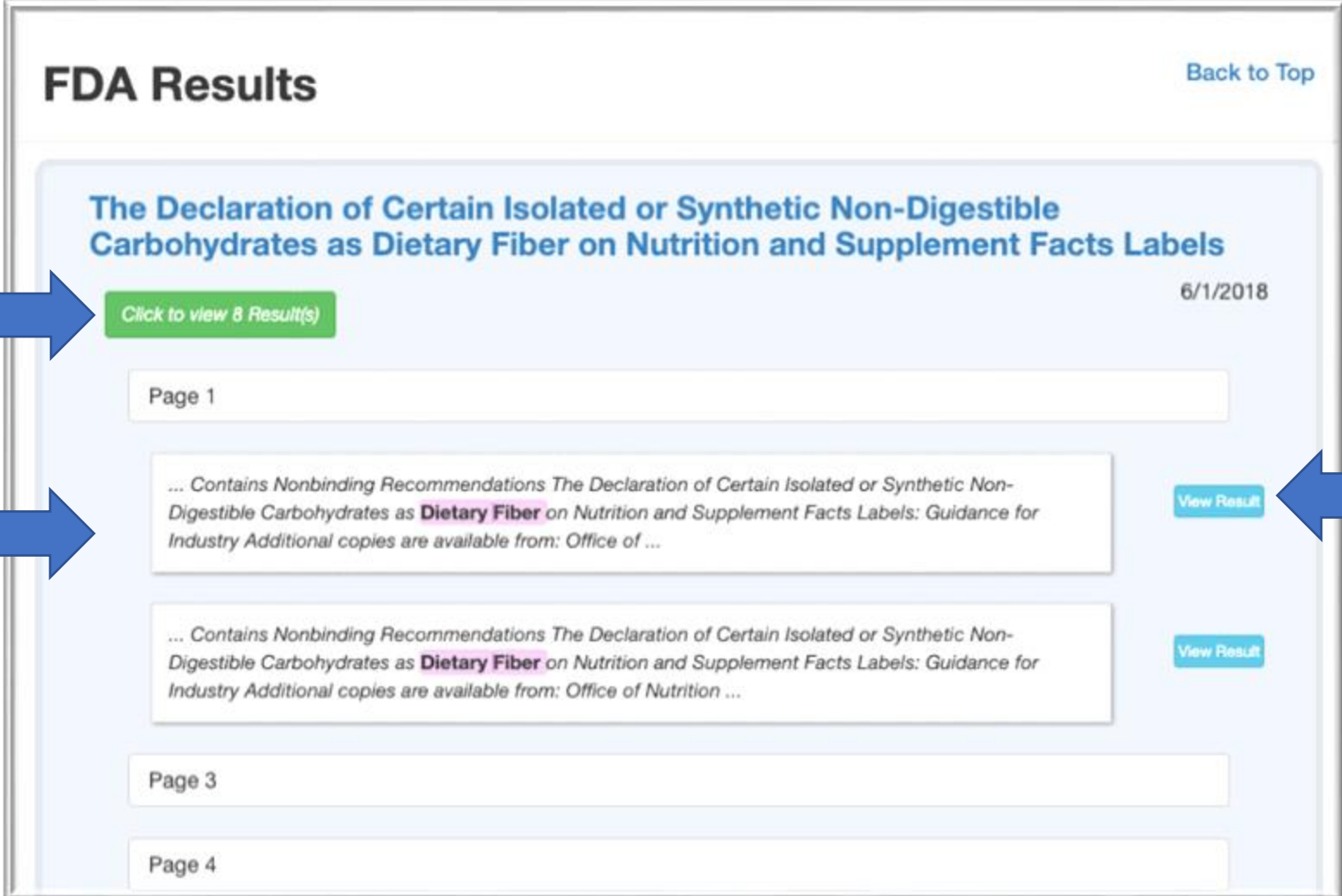
☒ FDA - 31 documents - 132 instances

☒ Other - 2 documents - 15 instances

☒ USDA - 19 documents - 75 instances



# Preview Result Details



The screenshot displays the 'FDA Results' interface. At the top left is the title 'FDA Results', and at the top right is a 'Back to Top' link. The main content area features a document title 'The Declaration of Certain Isolated or Synthetic Non-Digestible Carbohydrates as Dietary Fiber on Nutrition and Supplement Facts Labels' with a date '6/1/2018'. Below the title is a green button labeled 'Click to view 8 Result(s)'. A list of results follows, each with a preview of the document text and a 'View Result' button. The first result preview shows text about 'Nonbinding Recommendations' and 'Dietary Fiber'. The second result preview shows similar text. Below the results are page indicators for 'Page 1', 'Page 3', and 'Page 4'. Annotations with arrows point to specific elements: 'See how many matches per document' points to the green button; 'Preview document text' points to the first result preview; and 'Click View Results to open the full document' points to the 'View Result' button of the first result.

See how many matches per document

Click to view 8 Result(s)

6/1/2018

Page 1

... Contains Nonbinding Recommendations The Declaration of Certain Isolated or Synthetic Non-Digestible Carbohydrates as **Dietary Fiber** on Nutrition and Supplement Facts Labels: Guidance for Industry Additional copies are available from: Office of ...

View Result

Preview document text

... Contains Nonbinding Recommendations The Declaration of Certain Isolated or Synthetic Non-Digestible Carbohydrates as **Dietary Fiber** on Nutrition and Supplement Facts Labels: Guidance for Industry Additional copies are available from: Office of Nutrition ...

View Result

Page 3

Page 4

Click View Results to open the full document



# View Documents



Matches will be  
highlighted  
throughout the  
document

The Declaration of Certain Isolated or Synthetic Non-Digestible Carbohydrates as Dietary Fiber on Nutrition and Supplement Facts Labels: Guidance for Industry<sup>1</sup>

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

## I. Introduction

This guidance is intended to identify for manufacturers specific, additional isolated or synthetic non-digestible carbohydrates that we intend to propose adding to the list of those that meet our regulatory definition of “dietary fiber” (21 CFR 101.9(c)(6)(i)). This guidance also is intended to advise manufacturers of our intent to exercise enforcement discretion relative to the declaration of these isolated or synthetic non-digestible carbohydrates as a dietary fiber on Nutrition Facts and Supplement Facts labels, and for the use of a caloric value for polydextrose of 1 kcal/g, pending completion of a rulemaking regarding revising our regulations. The following isolated or synthetic non-digestible carbohydrates are subject to our intent to exercise enforcement discretion: mixed plant cell wall fibers; arabinoxylan; alginate; inulin and inulin-type fructans; high amylose starch (resistant starch 2); galactooligosaccharide; polydextrose; and resistant maltodextrin/dextrin.

This guidance is effective immediately because we have determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)).

# Bookmarking Favorites



**BOOKMARK IMPORTANT DOCUMENTS**

**Create Bookmark - Select Folder and Enter name**

Folder: Dietary Fiber

Name:

Page: 1

Search: dietary fiber

Save Cancel

## Questions and Answers

### Resources


- Science Review of Isolated and Synthetic Non-Digestible Carbohydrates (/food/labeling-nutrition/science-review-isolated-and-synthetic-non-digestible-carbohydrates)
- Labeling Guidance Documents (/labeling-nutrition)

### General Questions

- What actions has FDA taken on dietary fiber?



# Reference Bookmarked Documents

Home Search HelpLog Out

### Top Searches

- dietary fiber
- salmon
- nutrition label
- supplement label
- small packages



### Recently Viewed

- 2020.01.01 Questions and Answers on Dietary Fiber FDA
- Questions and Answers on Dietary Fiber
- Guidance for Industry Food Labeling Guide
- Title 21 - Volume 2 Chapter I Subchapter B - Food for Human Consumption Part 100 - GENERAL

### Bookmark Folders

- Dietary Fiber
- RE Labeling

### Dietary Fiber Bookmarks

Subject	Page	Search	Created	
<a href="#">Dietary Fiber Footnote</a>	30	dietary fiber	9/2/2021	
<a href="#">Questions and Answers on Dietary Fiber</a>	1	dietary fiber	9/3/2021	

ALL BOOKMARKED DOCUMENTS  
ARE SAVED HERE FOR QUICK  
AND EASY FUTURE ACCESS





# Genesis R&D Software

Genesis R&D Foods and Genesis R&D Supplements programs are designed to help users manage formulation and labeling processes and comply with federal requirements.

- Product Development
- Formulation Analysis
- Reporting
- Label Creation
- Regulatory Compliance

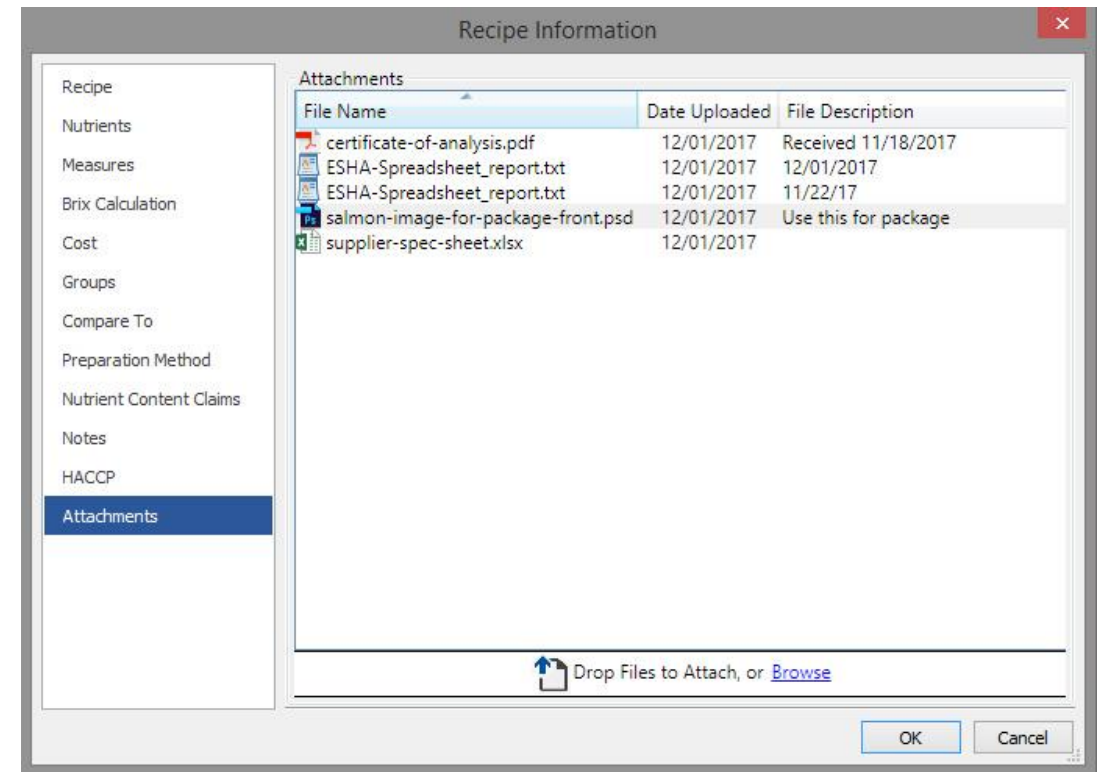
Supplement Facts		
Serving Size 1 Tablet Servings Per Container 60		
Amount Per Serving		% Daily Value
Vitamin A	900 mcg	100%
Vitamin C	90 mg	100%
Vitamin D	20 mcg (800 IU)	100%
Vitamin E	15 mg	100%
Thiamin	1.2 mg	100%
Riboflavin	1.3 mg	100%
Niacin	16 mg	100%
Vitamin B6	1.7 mg	100%
Folate	680 mcg DFE (400 mcg folic acid)	170%
Vitamin B12	2.4 mcg	100%
Biotin	30 mcg	100%
Pantothenic Acid	5 mg	100%
Choline	550 mg	100%
Fluoride	20 mg	†
† Daily Value not established		

Nutrition Facts	
8 servings per container	
Serving size	1 slice (59g)
Amount per serving	
Calories	180
% Daily Value*	
Total Fat 6g	8%
Saturated Fat 4g	20%
Trans Fat 0g	
Cholesterol 25mg	8%
Sodium 190mg	8%
Total Carbohydrate 28g	10%
Dietary Fiber 1g	4%
Total Sugars 15g	
Includes 14g Added Sugars	28%
Protein 3g	
Vitamin D 0mcg	0%
Calcium 55mg	4%
Iron 2mg	10%
Potassium 268mg	6%
*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.	



# REX + Genesis R&D Record-Keeping

- Genesis R&D users can attach documents to Recipes, Ingredients, Labels, and Food Menus.
- Various file types can be attached to a record including PDF, JPG, CSV, MP4, and more.





# GET STARTED TODAY!



Contact Us:

- 503-585-6242 x2
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- [esha.com/rex](https://esha.com/rex)

QUESTIONS?



## CONTACT US

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Training: [training@esha.com](mailto:training@esha.com)



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## HELPFUL RESOURCES

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eLearning Center: [esha.com/resources/esha-elearning-center/](https://esha.com/resources/esha-elearning-center/)

Blog: [esha.com/blog](https://esha.com/blog)

eNewsletter: <https://esha.com/esha-enewsletter/>