



FDA Public Workshop
The Nonprescription Drug Facts Label in a
Changing Consumer Marketplace 2021
“What’s Working/ What’s Not”

9 June 2021

Julie L. Aker, President & CEO
Concentrics Research

Highlights

- Specialty CRO, Site and Strategy Center
 - Over 35 years in business
 - Rx and OTC: Drugs, devices
 - **Voice of the consumer or patient**
 - Listen & Innovate
 - **Rx-to-OTC Switch**
 - Behavioral studies (LC, SS, AUS, HF)
 - Technology solutions
 - 150 specialized staff
 - Researchers
 - Telemedicine
 - Woman-owned Business (WBENC Certified)



Concentrics Research
Indianapolis, IN

Concentrics Center for Research
Indianapolis, IN



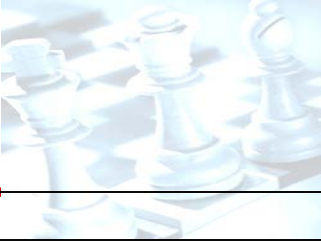
Concentrics Strategy Center
Parsippany, NJ





What's Working?

The Consumer Navigation Process...



In a study of 204 consumers to evaluate how OTCs are located, we learned that consumers use more than the DFL to find what they need:

- Therapeutic category
 - Aisle or online search
- Indication
 - PDP – front of the box or bottle
- Directions & Warnings
 - DFL – back of the box or bottle

White Paper: Consumer Navigation and Selection Behaviors for OTC Products in a Retail Setting
Julie Aker, MT (ASCP), Melissa Beck, BA, Sara Travis, BS, Jennifer Harris, BA, EMT

What's working with the DFL?



- Content
 - Purpose and ‘Uses’: Indication (*What does this medicine do?*)
 - Directions (*How do I use this medicine?*)
 - More focus on absolutes:
 - Do not use, Stop use, Uses, Directions
- Format
 - Familiar
 - Sections
 - White space
 - Judicious use of pictograms, highlighting and bolding



What's Not Working?

What's not working?



- Technical words (e.g., ingredients)
- Density
 - Navigation issues (eyes do not know where to go)
 - Long lists of warnings
 - Expectations for ALL information to be on DFL leading to peel back or “lift up” panels
 - Duplication – similar warnings before and after use
- Order of the DFL
 - Because Directions are at the end, warnings are often just scanned
- Side effects
 - Where are they?

What's not working



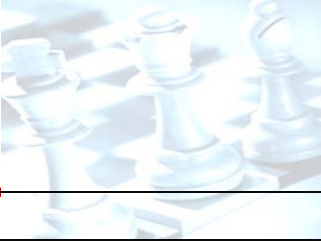
- Duplicative condition references before and after use
 - E.g., repeated references to a particular condition
 - Do not use if you have a history of X condition
 - Ask a doctor if you have a signs of X condition
 - Stop use if you have symptoms of X condition
- Warning wallpaper
 - Which warnings are really important? Some more important than others?
 - Are these requirements or recommendations?
 - Many people DO consult and depend on their doctor's input regardless of the labeling
 - Especially those with chronic medical conditions

What are we missing?



- More focus on the PDP than you think
- For the DFL, less is more
 - e.g., Think of Terms & Conditions and privacy statements and the density effect
- Decision-making often driven by:
 - Friends/family
 - Increasingly, by reviews online for people with similar conditions
 - Using what has worked in the past
- Assumptions that
 - Labeling is forced by attorneys, and these are recommendations (not requirements)
 - Not as strong as a prescription medication

Relevancy for special populations...



- Children & Elderly
 - Seeking relevant ages & dosing
- Limited Literacy/ESL
 - Seeking common words
- Certain medical conditions
 - Seeking relevant medical conditions
- Potential drug-drug interactions
 - Seeking relevant drugs

Affects on comprehension, self-selection and actual use?



- Comprehension
 - Lots of time to “find” information
 - Can lead to guessing or relying on past experience (incorrect responses but signals that they gave up)
- Self-selection
 - More focus on indication/condition: (“ruling in” criteria)
 - Less focus on warnings (“ruling out” criteria)
 - “ask a doctor” and “ask a doctor or pharmacist” often viewed as recommendations – consumers tend to default to what their doctor has told them.
- Actual use
 - Consumers do well overall
 - Focus more on Directions than changes in health over time
 - Adverse events (“stop use”) are common sense to most people



WHY is it Not Working?

The world changed...



Why do people use technology?



- **S**EARCHABLE/CUSTOMIZABLE
- **E**ASY
- **L**EARN
- **F**AST & **F**AMILIAR

Motivation to seek information that is relevant and applies to oneself

Feedback from Consumers on the DFL



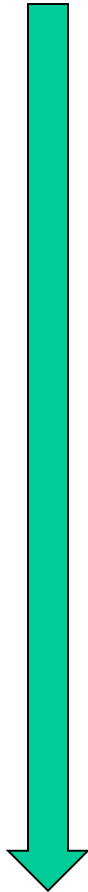
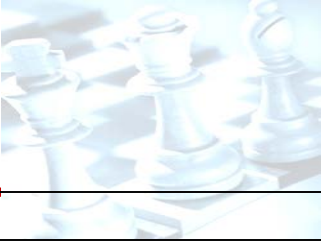
- Exterior Labeling:
 - *“I read it the first time I use it.”*
 - *“I use the front of the box to help me know what to buy!”*
- Finding key information on the DFL
 - *“Use more color!” “Use red for important things!”*
 - *“Text is too small!”*
- Sorting/Finding in a store:
 - Everyone has a different sorting method (e.g., nighttime/daytime, pregnancy, high blood pressure)

What about limited literacy?



- ~~Consumers do confer with doctors and many use health portals~~
 - *“I check with my doctor first...I have **MyChart on the computer**, so, send her a message” (01-103, Caucasian/Asian/Multiracial/Other, M, LL)*
- Google search
 - *“Start first, going to the allergies aisle and I take in all my options, and I look at the, which one is non-drowsy, which one is really drowsy, and um, which one is like 24 hours... **and I also do Google search...**” (02-009, African American, F, LL)*
- Highlighting key conditions is helpful
 - *“Like there’s one drug, it’s a cold medicine they’ve been advertising, if you have **blood pressure**, don’t take it, it’s a over the counter drug... I remember seeing it, and I think that was **very useful**.” (04-015, African American, F, LL)*
- Simplify
 - *“The ingredients. I know that they are the ingredients, but I wish there was **a way to break down the ingredients**. You know what I mean? Because some of the things you never even heard of, you know?... Stupefy it, dumb it down a little bit...sometimes even if I read it, I wouldn’t know what it is.” (05-007, Hispanic, F)*
- Nearly everyone, including those of limited literacy, use a smartphone
 - *“This **phone** right here, I can **ask it anything** I want, and it will tell me...” (01-301, African American, M)*

Intended vs. Actual Navigation



Drug Facts

Active ingredient (in each tablet)	Purpose
Chlorpheniramine maleate 2 mg	Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
 ■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat

Warnings
 Ask a doctor before use if you have
 ■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis
 ■ trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

When using this product
 ■ You may get drowsy ■ avoid alcoholic drinks
 ■ alcohol, sedatives, and tranquilizers may increase drowsiness
 ■ be careful when driving a motor vehicle or operating machinery
 ■ excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions	
adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours
children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours
children under 6 years	ask a doctor

Other information store at 20-25° C (68-77° F) ■ protect from excessive moisture

Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch



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Drugs.com represents the DFL information differently

- Drugs.com uses 2 approaches:

- Different Headings

Uses | Warnings | Dosage | What to avoid | Side effects | Interactions | FAQ

- Presentation of questions vs. statements

- E.g., What is this this medicine? What are the side effects?

Consumers search online for OTCs?



- *“I can search for the product I want.”*
- *“It’s faster.”*
- *“It’s more convenient.”*
- *“There is a symptom checker! I like that!”*

Online searches also commonly by category, then by brand

The image displays two screenshots of online searches for allergy medicines. The left screenshot is from Amazon, showing search results for "allergy medicines" with various filters on the left side, including "Brand" (Amazon Basic Care, Good Sense, Zyrtec, Claritin, Allegra, Boiron) and "Price" (Under \$25, \$25 to \$50, \$50 to \$100, \$100 to \$200, \$200 & Above). The right screenshot is from CVS pharmacy, showing search results for "allergy medicines" with filters for "Category" (Health & Medicine, Baby & Child, Home Health Care) and "Brand" (CVS Health, Allegra, Zyrtec, Claritin). Both screenshots have red circles highlighting the search terms and filter sections.





What Alternatives Could Work?

What would it take to improve the DFL?

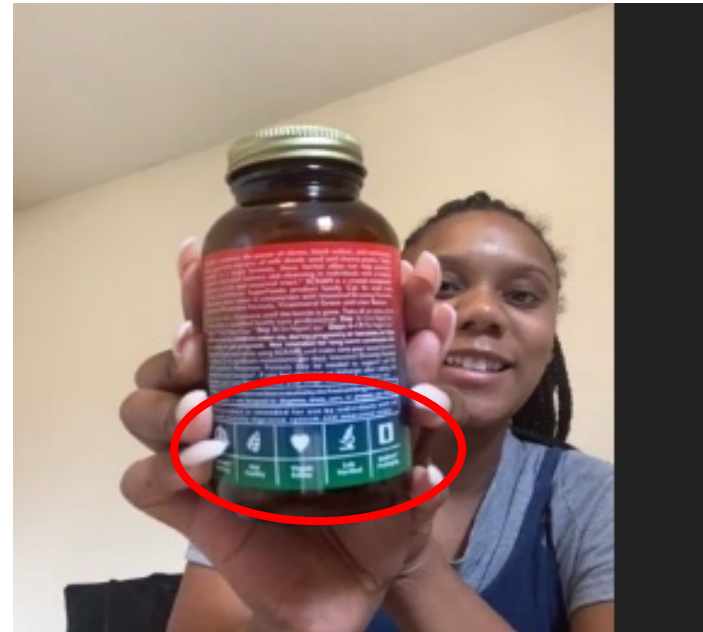


- Fewer words
- Pictures
- Plain language
- Search and find
- Relevancy by special populations

Consumers show examples of helpful labeling...

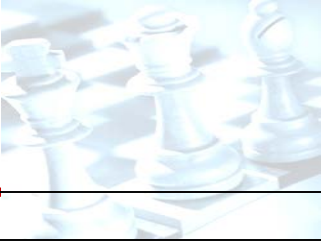


“I like the big words on the front of the box. It is easy to see the ingredients and what it does!”



“My supplements use pictures to show me key information!”

Pictures/icons can help



Would information in a different format with pictures help you search and find information about OTC medicines?



Do not take if:

- You have heart disease
- You are diabetic



Side effects may include:

- Dizziness
- Dry Mouth



ASK YOUR DOCTOR?

Ask a doctor before use if:

- You have high blood pressure



Stop use and ask a doctor if:

- You have chest pain



Ask a doctor or pharmacist before use if:

- You are taking an antibiotic

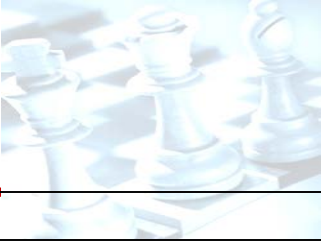


Directions

- Take 1 tablet
- Every day at the same time

In a recent study consumers of limited literacy, we tested the use of icons to signal parsing of key sections, we found that most of the participants liked having simple and recognizable icons point to key sections with simple text.

Alternative formats



Aker et al

127

Patient Information: What You Need to Know about Taking ORTHO TRI-CYCLEN™ (norgestimate/ethinyl estradiol)

Drug Name: ORTHO TRI-CYCLEN tablet

WHAT is it?
WHAT does it do?
HOW do I take it?
Possible side effects:

IMPORTANT WARNINGS
GET MEDICAL HELP
ASK A DOCTOR
FOLLOW DIRECTIONS

Use:
Important Warnings:
Tell Your Doctor:
Common Side Effects:
Directions for Use:

Drug approved by FDA 19XX
 Last Revised: May 2011

For more information, visit <http://www.ortho-tri-cyclen.com/ortho-tri-cyclen/>

We studied parsed information in novel formats with 83 participants. The results demonstrated that parsing helps one to navigate (locate) and understand the information. Both novel prescription Medication Guide formats tested better than the current approach.






Most people preferred the pictures...

Table 5. Use of icons.

	ORTHO TRI-CYCLEN (n = 25 respondents)		PARNATE (n = 20 respondents)		COUMADIN (n = 30 respondents)	
	n	%	n	%	n	%
How would you rate the use of pictures (or icons)?						
The pictures made it easier to find information.	19	76.0	22	78.6	27	90.0
The pictures made no difference in finding information.	5	20.0	5	17.9	3	10.0
The pictures made it more difficult to find information.	1	4.0	1	3.6	—	—

Aker J, Beck M, Papay JI, et al. Consumers Better Understand and Prefer Simplified Written Drug Information: An Evaluation of 2 Novel Formats Versus the Current CMI. *Therapeutic Innovation & Regulatory Science*. 2013;47(1):125-132. doi:10.1177/0092861512462371

Use of Steps, Icons and Instructions

Drug Facts	
Active ingredient (in each XX) Naloxone hydrochloride X mg	Purpose Emergency treatment of opioid overdose
Uses <ul style="list-style-type: none"> To "revive" someone during an overdose from many prescription pain medications or street drugs such as heroin This medicine can save a life 	
Directions	
 <p>1 CHECK</p>	Step 1: CHECK <ul style="list-style-type: none"> CHECK for a suspected overdose: the person will not wake up or is very sleepy or not breathing well <ul style="list-style-type: none"> yell, "Wake up!" shake the person gently if the person is not awake, go to Step 2
 <p>2 GIVE</p>	Step 2: GIVE 1st dose <ul style="list-style-type: none"> GIVE the 1st dose of this medicine <ul style="list-style-type: none"> Place the injector on the LEG above the knee and press down
 <p>3 CALL</p>	Step 3: CALL <ul style="list-style-type: none"> CALL 911 immediately after giving the 1st dose
 <p>4 WATCH/GIVE 2-3 Min</p>	Step 4: WATCH & GIVE <ul style="list-style-type: none"> WAIT 2-3 minutes after the 1st dose to give the medicine time to work <ul style="list-style-type: none"> if the person wakes up: Go to Step 5 if the person does not wake up: <ul style="list-style-type: none"> CONTINUE TO GIVE doses every 2-3 minutes until the person wakes up it is safe to keep giving doses
 <p>5 STAY</p>	Step 5: STAY <ul style="list-style-type: none"> STAY until ambulance arrives: even if the person wakes up GIVE another dose if the person becomes very sleepy again You may need to give all the doses in the pack
Warnings When using this product some people may experience symptoms when they wake up, such as shaking, sweating, nausea, or feeling angry. This is to be expected.	
Other information - store at room temperature. <small>advise insert tamper evident statement here</small>	
Inactive Ingredients	
Questions? <small>(phone number, website)</small>	

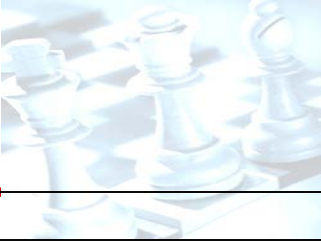
- Novel DFL created and tested in 710 participants by FDA for OTC Naloxone proved to be very effective in:*
- Guiding the order of the steps*
 - Using pictures to guide the instructions*
 - Using text to outline Uses, Directions and Warnings.*
- Note: The order was changed to include Uses and Directions First, followed by Warnings*

Cohen BR, Mahoney KM, Baro E, Squire C, Beck M, Travis S, Pike-McCrudden A, Izem R, Woodcock J. FDA Initiative for Drug Facts Label for Over-the-Counter Naloxone. N Engl J Med. 2020 May 28;382(22):2129-2136. doi: 10.1056/NEJMsa1912403. PMID: 32459923.



Can We Leverage Technology *Now*?

Nearly all Americans have smartphones



85% of all Americans have a smartphone and are using it daily for a variety of functions.

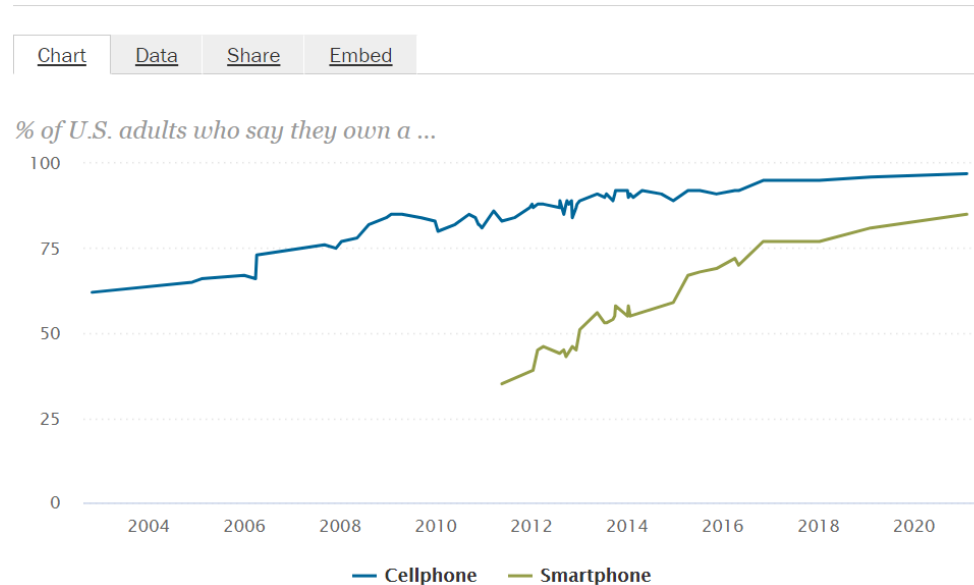


And they USE their smartphones...



Mobile phone ownership over time

The vast majority of Americans – 97% – now own a cellphone of some kind. The share of Americans that own a smartphone is now 85%, up from just 35% in Pew Research Center's first survey of smartphone ownership conducted in 2011.



Note: Respondents who did not give an answer are not shown.

Source: Surveys of U.S. adults conducted 2002-2021.

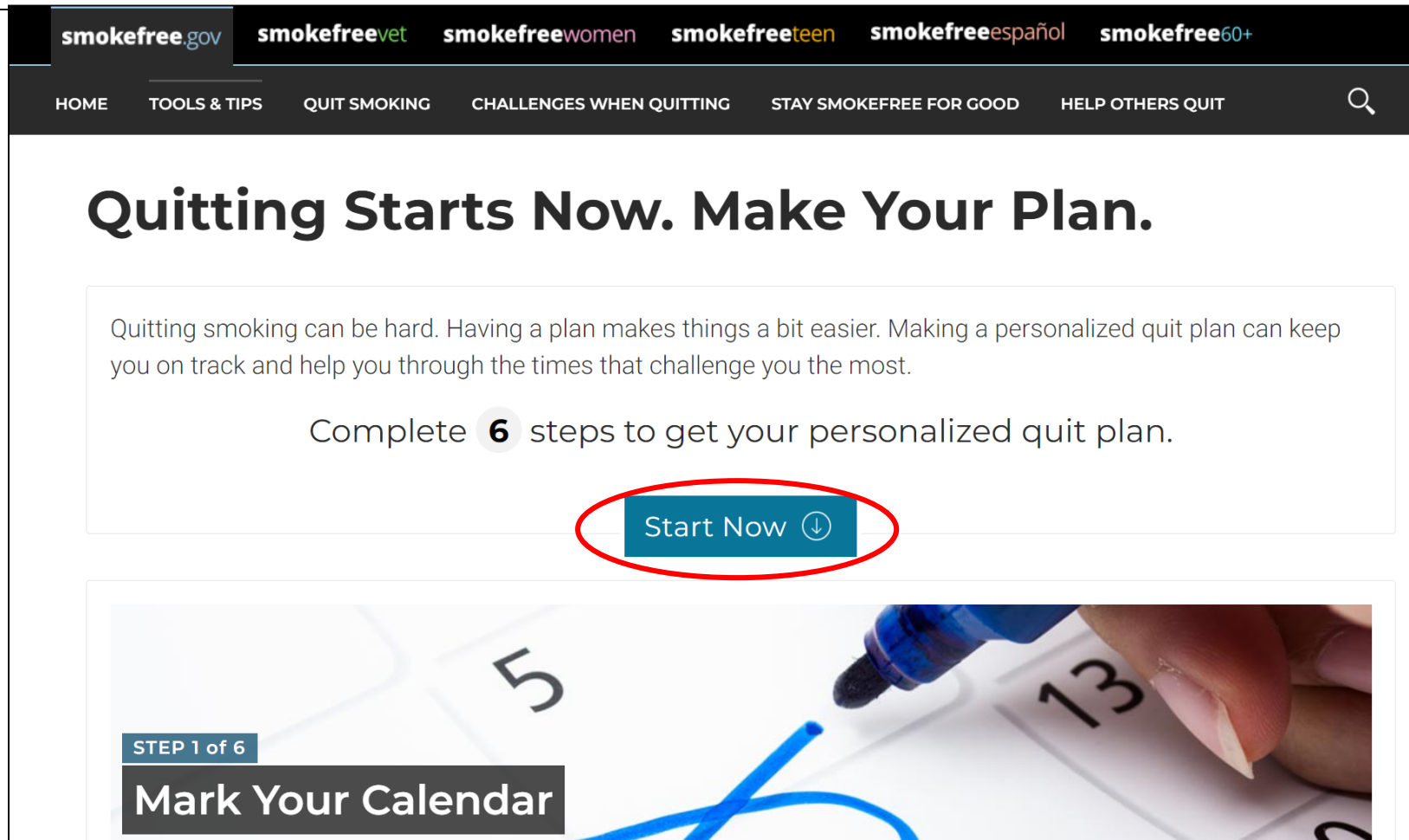
PEW RESEARCH CENTER

*In a recent study, in a general population of **936 consumers who were screened for a study, only 1.9%** (n=18) were unable to participate due to lack of technology (a device or a camera).*

*In another recent study, in a special population of **60 limited literacy consumers (Hispanic, African American and multi-cultural)**, participants stated they get their information on OTC medicines:*

- *Google search: **93%***
- *YouTube or social media: **77%***
- *Ask or watch commercials: **32%***

What about the DFL + links to dynamic websites?



The screenshot shows the top navigation bar of the smokefree.gov website with links for smokefree.gov, smokefreevet, smokefreewomen, smokefree teen, smokefreeespañol, and smokefree60+. Below the navigation bar are menu items: HOME, TOOLS & TIPS, QUIT SMOKING, CHALLENGES WHEN QUITTING, STAY SMOKEFREE FOR GOOD, and HELP OTHERS QUIT. The main heading reads "Quitting Starts Now. Make Your Plan." Below this is a paragraph: "Quitting smoking can be hard. Having a plan makes things a bit easier. Making a personalized quit plan can keep you on track and help you through the times that challenge you the most." Underneath is the text "Complete 6 steps to get your personalized quit plan." A blue button labeled "Start Now" with a downward arrow icon is circled in red. Below the button is a section titled "STEP 1 of 6 Mark Your Calendar" with a background image of a hand marking a calendar with a blue pen.

FDA's website,
<https://smokefree.gov/build-your-quit-plan>

The possibilities of DFL + QR codes...

ADVANCED COLLAGEN FORMULA

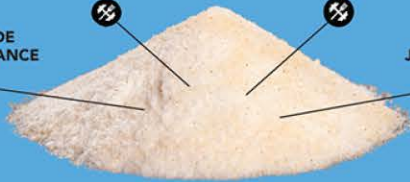
A single serving of Super Collagen Mix daily may help to:

BEAUTIFY & FIRM SKIN

STRENGTHEN TENDONS & LIGAMENTS

PROVIDE AGE DEFIANCE

IMPROVE JOINT HEALTH



Directions: Add one (1) serving to a smoothie, a protein shake, or 4-6oz of your beverage of choice. Mix well and enjoy!

Collagen Proprietary Blend: Hydrolyzed Collagen (Types I, II & III), Camu Camu (Fruit) Hyaluronic Acid, CoQ10, Lycopodium (Fruit) Extract, Aloe Vera Juice Powder, SOD (Superoxide Dismutase).


NOTE: THIS PRODUCT IS FILLED BY WEIGHT NOT VOLUME. KEEP IN A DRY PLACE. KEEP OUT OF THE REACH OF CHILDREN. THIS PRODUCT HAS NOT BEEN EVALUATED BY THE FDA. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, OR PREVENT ANY DISEASE. IF PREGNANT OR NURSING, CONSULT A HEALTH CARE PROVIDER. USE: 0420

Supplement Facts


Serving Size 6g (1 scoop)
Servings per container 30

Amount Per Serving	% Daily Value*
Calories 24	
Total Fat 0g	0%
Saturated Fat 0g	0%
Trans Fat 0g	0%
Cholesterol 0mg	0%
Sodium 1mg	0%
Total Carbohydrate 1g	0%
Dietary Fiber 1g	4%
Total Sugars 0g	0%
Added Sugars 0g	0%
Sugar Alcohols 0g	0%
Protein 5g	0%**
Vitamin A (Beta-Carotene) 900mcg	100%
Vitamin C (Ascorbic Acid) 200mg	222%
Vitamin D (Cholecalciferol) 40mg	200%
Vitamin E (dl-Alpha Tocopherol) 30mg	200%
Biotin D1% 50mcg	166%
Selenium (Chelate 20%) 1.2mg	2,181%
Collagen Proprietary Blend 5,727.85mg †	

*Percent Daily Values based on a 2,000 calorie diet. †Daily Value not established
**Collagen is not a complete protein source due to the absence of the essential amino acid, Tryptophan. Product is not a significant source of Protein or complete Amino Acids.



CSE+ APP
FOR CREATIVE WAYS TO USE THIS PRODUCT, DOWNLOAD OUR APP TO GAIN ACCESS TO OVER 600 DELICIOUS, HEALTHY RECIPES!



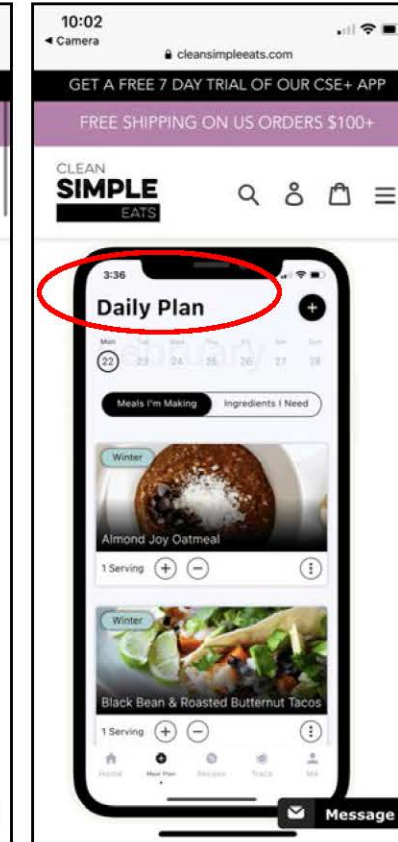
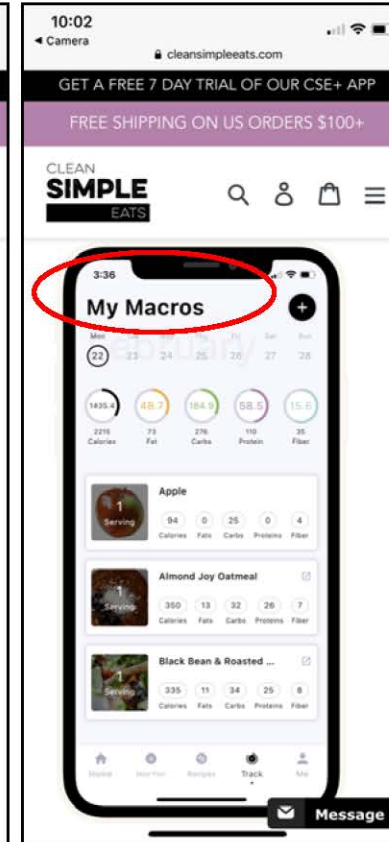
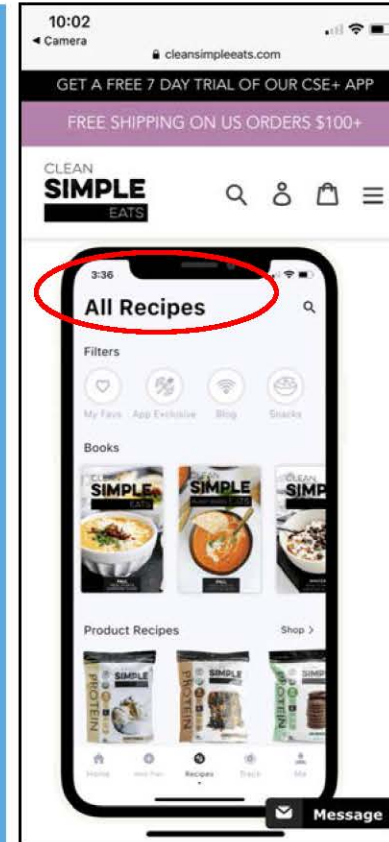
MADE IN USA

@cleansimpleeats
CLEANSIMPLEEATS.COM

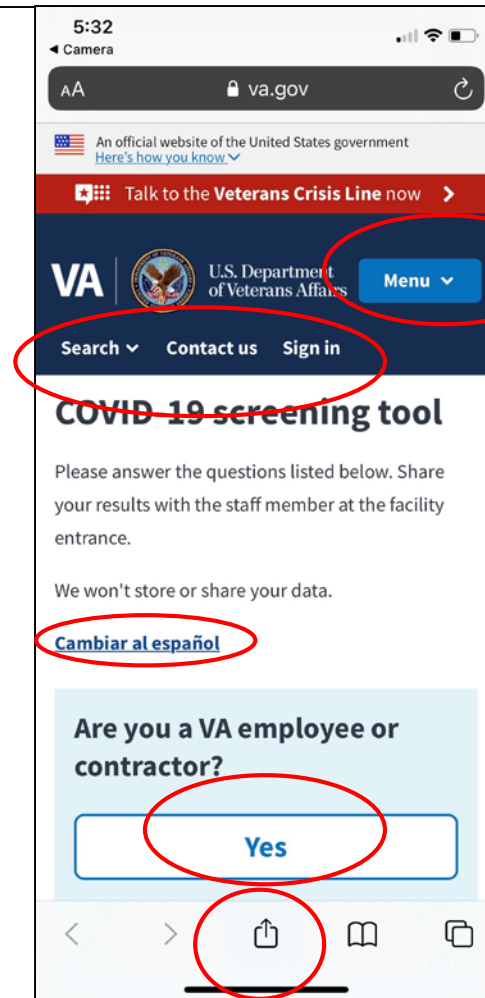
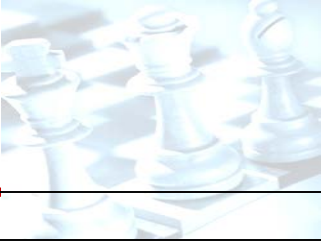


8 51068 00695 0

DISTRIBUTED BY:
CLEAN SIMPLE EATS
MANUFACTURED IN
NEPHI, UT 84648



DFLs + QR Codes can link to a survey...

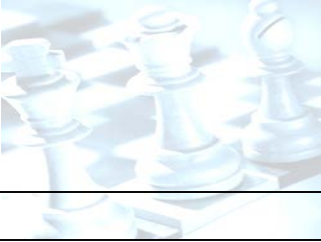


DFL + QR Codes can link to material to see & print



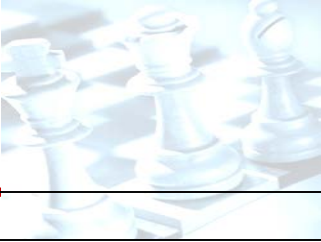
This QR Code links to a website with moving pages that provide information, a menu and the ability to print information.

Other considerations



- Does everything have to be on the DFL?
 - What about just self-selection criteria for “before use”?
 - More information could be found in an “Instructions for Use” approach or “Leaflet” inside the box or online.
 - What if the DFL used only key words and phrases and more information was found in a leaflet or survey through a QR code
 - Consider that many other countries use QR codes or other abbreviated methods for communicating information in a Leaflet at the point of purchase
 - Consider that the additional information could be presented in alternate languages
 - What is key icons could be used?
 - Could we leverage key icons on the PDP and/or DFL?
 - Could customized DFLs be highlighted to show focus for special populations?

Pulling it all together



- We know what's not working
 - Current DFL is becoming too complex
 - It is difficult to find key information or what is MOST important
 - The order is not intuitive to most consumers
 - Uses, Directions, then Warnings
 - Add “side effects” and use plain language throughout
- We know what could work now and, in the future,
 - Parsed information and icons can help
 - Consider short-term technology aids such as barcodes or QR codes for quick access to information
 - In the future, consider customization by medical conditions and other medications based on the consumer's medical history and use of apps.




Concentrics Research

“Transforming Client Centered Strategies”

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