Printer: CDPEDQ5
User: STEPPERH
Date - Time: 25-Feb-2021 04:20 PM
Total Number of Cases (Non-Esub): 12
Total Number of Pages: 80
Print Job Number: 23772

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Processed Case Id's for Images:
18029697 18031315 18058526 18071321 18079070 18086811 18092378 18099295 18113306 18113963 18117937 18119463

Failed Case Id's for Images:

Total Failed Cases: 0

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	15-Jul-2020	CTU Received Date	15-Jul-2020
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

	What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
	Date the problem occurred	01-May-2020
	Serious	Yes
	Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident(Please Describe Below)
	Other serious/important medical incident(Please Describe Below)	Permanent Blurred Vision

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

My 13yo daughter has had perfect vision at each check up, could always read stuff across the room even small letters. In early May she complained that she couldn't read the clock because it was blurry, we then realized that everything was blurry, including larger text. Because of Covid, we have not been able to get her seen by a specialist. We purchased Blumen brand hand sanitizer from (b) (6) in April and we have all unknowingly experienced symptoms after using it, headaches, dizziness, nausea, etc, but I fear her sudden vision loss is a direct result from using this and she hasn't had any improvement over the past 2 months.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	

More Information Available?	

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	Yes
Do you have a picture of the product? (check yes if you are including a picture)	No

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	Drug/Biologic		
This report is about	Cosmetic,Dietary Supplement or Food/Medicinal Food		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Blumen Hand Sanitizer (18 oz.)		
Name of the company that makes (or compounds) the product	Blumen		
Product Type(check all that apply)	☑ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
Strength		If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?	No		
Did the problem return if the person started taking or using the product again?	Doesn't Apply		

Drug Therapy 1 of 1

Expiration date			
Lot number			
Dosage Form			
Quantity	Other	If Other	1 squirt
Frequency	As needed	If Other	
How was it taken or used	Topical	If Other	
Date the person first started taking or using the product			
Date the person stopped taking or using the product			

Give best estimate of duration	2 Month	
Is therapy still on-going?		

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

To sanitize hands when washing not possible

Returned to Manufacturer On	

Section D - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	

Section E - About the Person Who Had the Problem

Person's Initials	(b) (6)
Gender	Female
Age (specify unit of time for age)	13 Year(s)
Date of Birth	
Weight	81 kg
Ethnicity (Choose only one)	Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaskan Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Asthma

Please list all allergies (such as to drugs, foods, pollen or others)

Milk

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

Ventolin Inhaler as needed

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

NA

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	

	Today's date	15-Jul-2020	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	16-Jul-2020	CTU Received Date	16-Jul-2020
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Date the problem occurred	23-May-2020
Serious	Yes
Did any of the following happen? (Check all that apply)	☑ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident(Please Describe Below)

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

Throwing up felling dizzy extremely bad headaches fever

Relevant Test/Laboratory Data 1 of 2

Test Name	CAT SCAN	Test Date	(b) (6)
Test Result	Clear	Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Relevant Test/Laboratory Data 2 of 2

Test Name	CORONA TEST	Test Date	(b) (6)	
Test Result	Neg	Test Unit		
Low Test Range		High Test Range		
More Information Available?				

Additional Comments

Was very sick blurred vision throwing up and bad head ache still experiencing blurred vision

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	Yes
Do you have a picture of the product? (check yes if you are including a picture)	Yes

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	Drug/Biologic		
This report is about	Drug		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Blumen hand sanitizer		
Name of the company that makes (or compounds) the product	Blumen		
Product Type(check all that apply)	☑ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
Strength		If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes		
Did the problem return if the person started taking or using the product again?	Doesn't Apply		

Drug Therapy 1 of 1

Expiration date			
Lot number			
Dosage Form			
Quantity		If Other	

	Frequency	As needed	If Other		
	How was it taken or used	Topical	If Other		
	Date the person first started taking or using the product	15-May-2020			
	Date the person stopped taking or using the product	15-Jul-2020			
	Give best estimate of duration				
	Is therapy still on-going?				

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Pandemic

	Returned to Manufacturer On	

Section D - About the Medical Device

	Name of medical device	
	Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

	Model Number	
	Catalog Number	
	Lot Number	
	Serial Number	
	UDDI Number	
	Expiration date	
	Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	

Section E - About the Person Who Had the Problem

	Person's Initials	(b) (6)
	Gender	Female
	Age (specify unit of time for age)	39 Year(s)
	Date of Birth	
	Weight	99 kg
	Ethnicity (Choose only one)	Hispanic/Latino
	Race (Check all that apply)	☐ American Indian or Alaskan Native ☐ Native Hawaiian or Other Pacific Islander

	☐ Asian ☑ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

None known

Please list all allergies (such as to drugs, foods, pollen or others)

None known

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

Smoke

List all current prescription medications and medical devices being used.

None

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

None

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)

	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	16-Jul-2020	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

blumen
Clear
ADVANCED
HAND
SANITIZER
70% ALCOHOL
EXTRA SOFT
FREE
7.5 fl oz / 221ml
99.9%

blumen
Clear
ADVANCED
HAND
SANITIZER
70% ALCOHOL
EXTRA SOFT
FREE
7.5 fl oz / 221ml
99.9%

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	22-Jul-2020	CTU Received Date	22-Jul-2020
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

	What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
	Date the problem occurred	15-Apr-2020
	Serious	Yes
	Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☑ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident(Please Describe Below)
	Other serious/important medical incident(Please Describe Below)	Neurological

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

Migraines Hand Tremors Nausea Memory loss Loss of appetite Blurred vision Memory loss impacting school

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	

	More Information Available?	

Additional Comments

Section B - Product Availability

	Do you still have the product in case we need to evaluate it?	Yes
	Do you have a picture of the product? (check yes if you are including a picture)	Yes

Section C - About the Products 1 of 1

	Suspect	Yes		
	Primary?	Yes		
	Type	Drug/Biologic		
	This report is about	Cosmetic,Dietary Supplement or Food/Medicinal Food		
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Blumen Clear Advanced Hand Sanitizer		
	Name of the company that makes (or compounds) the product	4E Brands		
	Product Type(check all that apply)	☑ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
	Strength	Other	If Other	17 fl oz
	NDC number			
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	No		
	Did the problem return if the person started taking or using the product again?	Doesn't Apply		

Drug Therapy 1 of 1

	Expiration date	22-Apr-2023		
	Lot number	2877		
	Dosage Form			
	Quantity		If Other	
	Frequency	Other	If Other	multiple times a d
	How was it taken or used	Topical	If Other	
	Date the person first started taking or using the product	15-Apr-2020		
	Date the person stopped taking or using the product	22-Jul-2020		

Give best estimate of duration	
Is therapy still on-going?	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

to prevent the spread of COVID-19

Returned to Manufacturer On	

Section D - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	

Section E - About the Person Who Had the Problem

Person's Initials	(b) (6)
Gender	Female
Age (specify unit of time for age)	39 Year(s)
Date of Birth	
Weight	81.45 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☑ American Indian or Alaskan Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☑ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Asthma Seizure disorder Psoriasis

Please list all allergies (such as to drugs, foods, pollen or others)

latex Pineapples

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	

	Today's date	22-Jul-2020	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	


HAND SANITIZER
Drug Facts
Active Ingredients
Alcohol 70% V/V

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	26-Jul-2020	CTU Received Date	26-Jul-2020
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Date the problem occurred	03-Apr-2020
Serious	Yes
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☑ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident(Please Describe Below)

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

I was feeling extremely fatigued and nauseated. I had diarrhea, upset stomach, pain and bruising on my stomach, a rash on my shoulders that moved to my chest, arms, hands and down onto my stomach,(was painful and itchy) my neck, shoulders,and low back were sore and achy, I had a cough that came and went, had trouble breathing, with slight tightness in my chest, sore throat, and some sinus pressure. 04/06/2020 - Due to my symptoms, I decided to go see the doctor. I was referred to Dr. (b) (6) She requested Lab tests. They were Negative. She prescribed me Prednisone. The rash and symptoms did not go away. I continued to feel very unwell for the rest of April and May. I didn't know what was happening with my health.I thought perhaps I had Coronavirus? (b) (6) I got a COVID 19 test. It was Negative.06/11/2020 - I had a doctor's video call with Dr. (b) (6) I told him how I was feeling even worse than before. He requested Lab tests 06/11. They were Negative and a Stomach Ct scan 06/19/ that came back Negative. He prescribed me Prednisone. 06/26- 06/28 - I was feeling even worse and as though my immune system was fighting itself. I had black and painful stools, constant abdominal pain, nausea, discomfort, swelling all over my body, a burning sensation from my abdomen up to my chest, canker sores appeared suddenly in my mouth, red, sore and painful throat and gums, my eyes were sunken with bags underneath, achy, painful and my vision was blurred, ear pain, my face, eyes, chin, and neck were swollen, I was fatigued with weakness in my legs and feet. My hands and toes hurt. I felt so exhausted that I didn't have the energy to do anything. I felt as though my body was completely shutting down. * I still do.06/29/2020 - I was referred to Dr. (b) (6) She listened to my concerns by video call and said that she thought perhaps I had Mononucleosis. She had some Lab tests ran 07/01. They were Negative. She

prescribed Pantoprazole and Sucralfate to calm my abdominal symptoms.07/09/2020 - Dr. (b) (6) requested a Mammogram. The results came back All Clear. 07/10/2020 - Dr. (b) (6) suggested I go see a Dermatologist. I saw Dr. (b) (6) He seemed concerned about my rash. He diagnosed the Folliculitis on my arms, (of which I had previously) but didn't seem to know why I was experiencing the rash on my upper thighs and stomach. The rash looked very different from the rest,(almost shingle-like and crusted). Dr. (b) (6) had a nurse do an allergy test on me. I am slightly allergic to peanuts, penicillin, and Russian thistle. He prescribed me an Ephiphrine Injectionjust in case of an emergency. He also prescribed me a Triamcinolone and Silver Sulfadiazine cream, Cephalexin, and Fluconazole tablets. 07/13/2020 - Dr. (b) (6) requested more Lab tests. They were Negative,(except for previous exposure to Cold Sores). 07/15/2020 - I met with Dr (b) (6) in his office and I explained how my eyes were painful, blurred, swollen, sunken and baggy. He suggested going to see an Eye doctor and have the pressure in my eyes checked. 07/16/2020 - I went to see Dr. (b) (6) a Gastroenterologist. He was extremely concerned as to why I had black stools, pain in my abdomen, diarrhea, burning in my abdomen and chest, and suggested that I get a Colonoscopy and an EGD done as soon as possible. Dr. (b) (6) prescribed Pantoprazole 2x day.Future Appointments:07/27/2020 - Eye Pointment at (b) (6) with Dr. (b) (6) to check vision, eye pressure,and any permanent damage.07/30/220 - Brain scan at (b) (6) 08/07/2020 - Dermatologist Follow Up with Dr. (b) (6) 08/11/2020 - Gastroenterologist Procedures - Colonoscopy and EGD with Dr. (b) (6) at (b) (6) 10/21/2020 - Gastroenterologist Follow Up with Dr (b) (6) * I stopped using Blumen hand sanitizer on Friday the 25th of July and I am still experiencing many of the same health issues and symptoms. (b) (6)

Relevant Test/Laboratory Data 1 of 8

Test Name	COMPLETE BLOOD COUNT	Test Date	06-Apr-2020
Test Result		Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Relevant Test/Laboratory Data 2 of 8

Test Name	AUTOMATED DIFFERENTIAL	Test Date	06-Apr-2020
Test Result		Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Relevant Test/Laboratory Data 3 of 8

Test Name	GENERAL CHEMISTRY	Test Date	06-Apr-2020
Test Result		Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Relevant Test/Laboratory Data 4 of 8

Test Name	SEROLOGY	Test Date	06-Apr-2020
Test Result		Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Relevant Test/Laboratory Data 5 of 8

Test Name	CELIAC DISEASE	Test Date	11-Jun-2020
Test Result		Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Relevant Test/Laboratory Data 6 of 8

Test Name	RHEUMATOID ARTHRITIS	Test Date	11-Jun-2020
Test Result		Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Relevant Test/Laboratory Data 7 of 8

Test Name	CCP ANTIBODIES IGG/IGA	Test Date	11-Jun-2020
Test Result		Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Relevant Test/Laboratory Data 8 of 8

Test Name	AMYLASE, LIPASE SERUM	Test Date	11-Jun-2020
Test Result		Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	Yes
Do you have a picture of the product? (check yes if you are including a picture)	Yes

Section C - About the Products 1 of 2

Suspect	Yes
Primary?	Yes
Type	Drug/Biologic
This report is about	Cosmetic,Dietary Supplement or Food/Medicinal Food
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Blumen - clear advanced hand sanitizer
Name of the company that makes (or compounds) the product	Blumen - 4e Brands North America,
Product Type(check all that apply)	☑ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic

		☐ Biosimilar		
	Strength	70% Ethyl Alcohol ml millilitre(s)	If Other	
	NDC number	814266024096		
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	No		
	Did the problem return if the person started taking or using the product again?	Doesn't Apply		

Drug Therapy 1 of 1

	Expiration date	20-Apr-2023		
	Lot number	2511		
	Dosage Form			
	Quantity		If Other	
	Frequency	As needed	If Other	
	How was it taken or used	Topical	If Other	
	Date the person first started taking or using the product	01-Apr-2020		
	Date the person stopped taking or using the product	24-Jul-2020		
	Give best estimate of duration			
	Is therapy still on-going?	Yes		

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

We wanted to keep hands clean due to Covid 19.

Section C - About the Products 2 of 2

	Suspect	Yes		
	Primary?			
	Type	Drug/Biologic		
	This report is about	Cosmetic,Dietary Supplement or Food/Medicinal Food		
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Blumen - clear advanced hand sanitizer		
	Name of the company that makes (or compounds) the product	Blumen - 4e Brands North America		
	Product Type(check all that apply)	☑ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
	Strength	70% Ethyl Alcohol ml millilitre(s)	If Other	
	NDC number	814266024096		

Did the problem stop after the person reduced the dose or stopped taking or using the product?	No	
Did the problem return if the person started taking or using the product again?	Doesn't Apply	

Drug Therapy 1 of 1

Expiration date	22-Apr-2023		
Lot number	2876		
Dosage Form			
Quantity	Other	If Other	1 Ounce(s)
Frequency	As needed	If Other	
How was it taken or used	Topical	If Other	
Date the person first started taking or using the product			
Date the person stopped taking or using the product			
Give best estimate of duration	4 Month		
Is therapy still on-going?			

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

To keep our hands clean due to Covid 19.

Returned to Manufacturer On	

Section D - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	

Section E - About the Person Who Had the Problem

Person's Initials	(b) (6)
Gender	Female
Age (specify unit of time for age)	50 Year(s)
Date of Birth	
Weight	76.5 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaskan Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

None

Please list all allergies (such as to drugs, foods, pollen or others)

A slight allergy to peanuts, penicillin, and Russian thistle.

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

I have a glass of wine in the evening with dinner.

List all current prescription medications and medical devices being used.

Due to Symptoms, I am taking Cephalexin, Pantoprazole, Fluconazole, Triamcinolone cream, and Silver Sulfadiazine cream.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

I stopped taking all Vitamins and Vitamin C by the advice of the Gastroenterologist in preparation for my Colonoscopy and EGD procedures coming up in Aug..

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	

	Title		
	Last name	(b) (6)	
	Middle Name		
	First name	(b) (6)	
	Number/Street	(b) (6)	
	City	(b) (6)	
	State/Province	(b) (6)	
	Country	UNITED STATES	
	ZIP or Postal code	(b) (6)	
	Telephone number	(b) (6)	
	Email address	(b) (6)	
	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	26-Jul-2020	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	


blumen
Clear
ADVANCED
HAND
SANITIZER
with 70% ALCOHOL
EXTRA SOFT
with GLYCERIN & ALOE
KILLS UP TO 99.9% OF GERMS
PARABENS & TRICLOSAN FREE
blumen
Clear
ADVANCED
HAND
SANITIZER
with 70% ALCOHOL
EXTRA SOFT
with GLYCERIN & ALOE
KILLS UP TO 99.9% OF GERMS
FREE

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	27-Jul-2020	CTU Received Date	27-Jul-2020
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Date the problem occurred	31-May-2020
Serious	Yes
Did any of the following happen? (Check all that apply)	☑ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident(Please Describe Below)

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

May 16 2020, while visiting (b) (6) in (b) (6) I came by the Blumen hand sanitizer. I purchased 2 bottles, one for the home and one for my work car. I use this product 3-5 times a day 5 days a week, on my hands, arms and even on the steering wheel of the work car, grabbed food with my hand still wet from that stuff, inhaled it while using it in a closed hot car. (b) (6) I woke up the same dizzy and not well. At that time, I decided to head to the ER. There they gave a bunch of tests and came out with Vertigo diagnosis. They gave me meds and told me to look on line and do the Epley maneuvers to reposition the Crystals in my ear. I did as recommend and felt better... but still there was something off, I was not feeling 100 %. I went through the month of June feeling a bit off, a little dizzy, not well overall. June 22 2020 I took the week of work for a little vacation. That week I felt ok but not 100 %. We were at the beach for a few days. June 25, I went to (b) (6) for a swim. I usually hit the springs and swim and dive for about 45 ? 60 minutes. This time I got in the water and after about 10-15 minutes I was feeling light headed and out of breath. I got out of the water and felt this strange feeling in my Plexus (center of my chest) . It felt hot when my body was cold from the 72-degree spring water. It felt like something was burning in my plexus, starting in the center and spreading out to the sides of my chest. I sat down and waited to regain my breath. I figured I was tired and since I had not been feeling well for a while, that was a bad day for the springs. I had never felt anything like that before. (b) (6) I woke up at 4:30am sweating feeling hot, got up and was very dizzy. Went to the living room, had my coffee and was just not feeling well, dizzy, had some heart palpitations, urinating constantly, had some ringing in my ears, fatigue, trouble focusing. Scared I returned to the ER. Again, a bunch of tests and nothing was found. They gave me a

vertigo dizziness diagnostic. July 6, I went to work but was feeling quite dizzy. I picked up my coworker and asked him to drive as I was not well. The day included a video shoot in a boat ride and dive for scalloping. I asked my coworker to take the boat trip without me as I was in no condition for such a physical day. July 7 Saw my Dr. regarding the dizziness. He referred me to a physical therapist to work with the Epley exercise to reposition crystals in my ear. July 13 and 17 were my PT sessions. As we tried to determine what side was the one affected, I really couldn't tell if I was getting any results. There was a different kind of dizziness. Different from when I was at the (b) (6) office. But with no other options I just assumed that I had some residual loose crystals left and that was normal to feel that way. Days after the PT, I still had this light dizziness. July went by, again I was ok working but not feeling 100 %. Sometimes I would wake up and feel as if I had a 6 pack of beer. A strange kind of dizziness. Days after the PT, I still had this light dizziness. July went by, again I was ok working but not feeling 100 %. Sometimes I would wake up and feel as if I had a 6 pack of beer. A strange kind of dizziness. July 22 2020 I was feeling good, and even went for a walk the day before. I decided to do my lawn. It was cloudy so I figured it was safe enough. I finished and sat down to drink some water and felt very light headed to the point I felt I was going to faint. Got up, took a shower and sat down to watch TV. Not feeling well. (b) (6) Again I woke up 4 am in a sweat and dizzy, got up, grabbed a coffee and sat on the couch. Had strange dizziness, hot flashes, pain on my chest, fatigue, frequent urination, palpitations, light headed, ringing in my ear. So, I got scared and went to the ER Again. Contines ....

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date	
Test Result		Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Additional Comments

...At the ER the story repeats itself. Bunch of tests, nothing conclusive. This time they told me to go see my Dr. next day. June 24 Saw my Dr. After the all the list of symptoms, they could not tell me what was wrong and that we will have to start investigating by parts and referred me to a cardiologist. So, the same day when I got back from my Dr. picked up the mail and got a letter from (b) (6) telling me that the hand sanitizer, I bought with them is on a recall list for Methanol contamination. I started to read about Methanol poisoning and there are many similarities to what I am going through. Also, the coincidental feel better feel worse timing. I would feel good a bit then I would get worse again probably from not using the product over the weekend would get me feeling better than Monday rolls in and I unknowingly started poisoning myself again. Now the hospital never told me I had Methanol poisoning, but also, they were not looking for that either. As far as I can understand from my readings, it is not easily detected if you are not looking for that. My wife asked me then, why she was not sick from the Methanol. When I checked the bottle in her car was the one, I purchased later and was from a different lot, not on the recall list. Could I have been exposed to enough Methanol to be sick? I do not know the answer. But I also do not like the coincidences. Were symptoms confused with Vertigo? Was the Vertigo brought about due to the Methanol in my system? Without any real medical proof of this poisoning, I have few answers. I have stopped using the product and will see if these strange symptoms will go away. I noticed that my Nearsightedness has gotten somewhat worse and my eyes are more sensitive to light. July 27 96 hours after last Hand sanitizer usage feeling better but not 100%

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	Yes
Do you have a picture of the product? (check yes if you are including a picture)	Yes

Section C - About the Products 1 of 1

Suspect	Yes
Primary?	Yes
Type	Drug/Biologic
This report is about	Cosmetic,Dietary Supplement or Food/Medicinal Food
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Blumen clear Advanced hand sanitizer

Name of the company that makes (or compounds) the product	4e Brands Northamerica LLC			
Product Type(check all that apply)	☑ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar			
Strength	Other	If Other	v/v	
NDC number				
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes			
Did the problem return if the person started taking or using the product again?	Doesn't Apply			

Drug Therapy 1 of 1

Expiration date	22-Apr-2023		
Lot number	2890		
Dosage Form			
Quantity	Other	If Other	1 pump
Frequency	As needed	If Other	
How was it taken or used	Other	If Other	Wet hands thoroughly with product & rub
Date the person first started taking or using the product	18-May-2020		
Date the person stopped taking or using the product	23-Jul-2020		
Give best estimate of duration			
Is therapy still on-going?			

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Keep hands clean due to corona virus epidemic

Returned to Manufacturer On	

Section D - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Model Number	
Catalog Number	

Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	

Section E - About the Person Who Had the Problem

Person's Initials	(b) (6)
Gender	Male
Age (specify unit of time for age)	48 Year(s)
Date of Birth	
Weight	9.9 kg
Ethnicity (Choose only one)	Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaskan Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Hypothyroid Eye Keratitis

Please list all allergies (such as to drugs, foods, pollen or others)

Zpack Shell fish

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

In 48 years I've only been in an ER for a foot ligament injury and my calf injury. Those were about 28-30 years apart. I am quite healthy, drink moderately do not smoke. I bike, I walk, swim and eat regularly healthy wholesome foods.

List all current prescription medications and medical devices being used.

Levothyroxine 150, Acyclovir 400

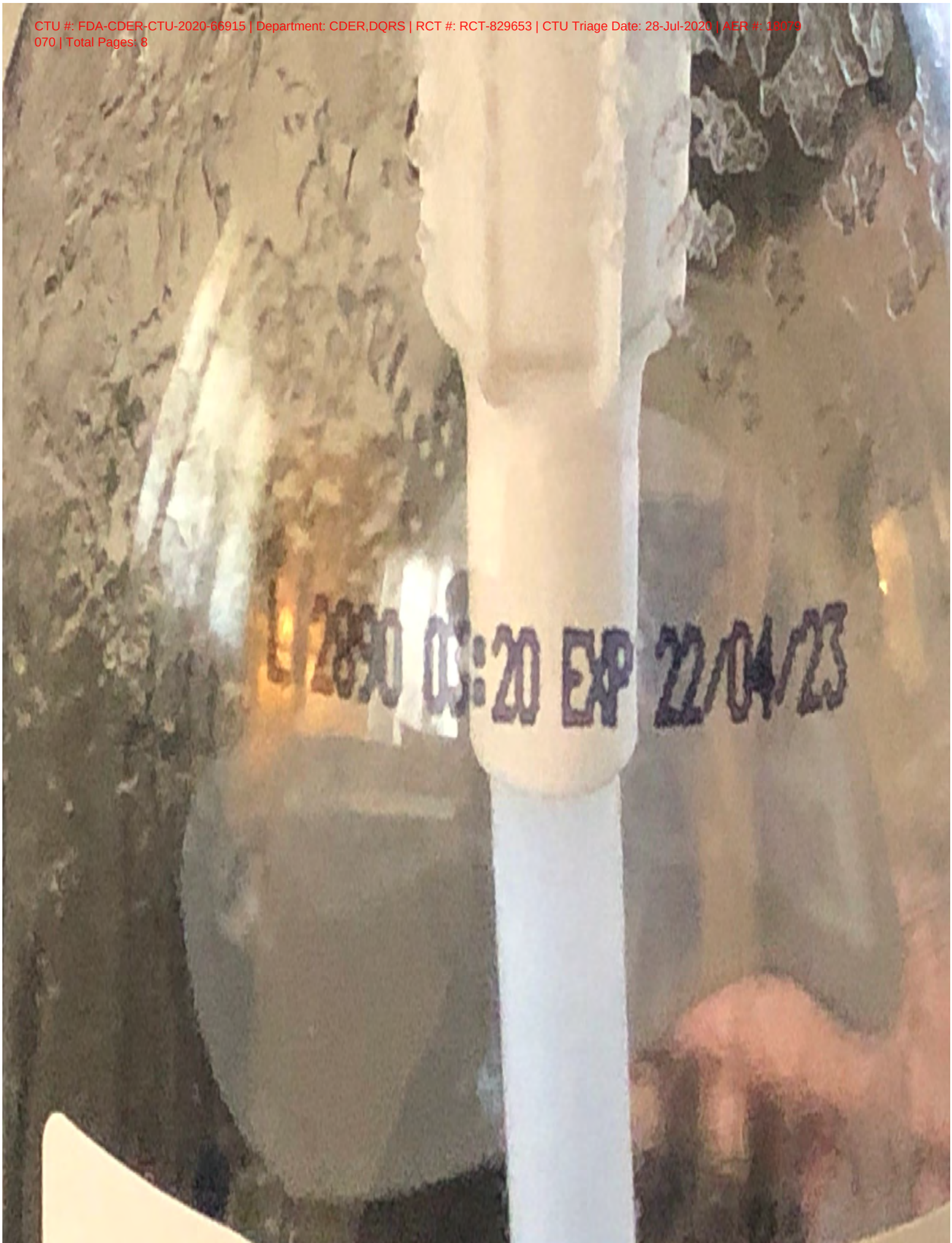
List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Multi vitamins Kirland, Lysine 1000, Baby aspirin 81	

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	27-Jul-2020
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes


L 2890 03:20 EXP 22/04/23
blumen
HAND SANITIZER
Drug Facts
Active ingredients.....Purpose
Ethyl Alcohol 70% v/v .....Antiseptic
Uses ·Hand sanitizer to help decrease bacteria on the skin. · When water, soap & towel are not available. ·Recommended for repeated use.
Warnings For external use only.
Flammable. Keep away from fire or flame.
Do not apply around eyes. Do not use in ears & mouth.
When using this product, avoid contact with eyes. In case of contact flush eyes with water.
Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours.
Keep out of reach of children. Children must be supervised in use of this product.
Directions ·Wet hands thoroughly with product. Briskly rub hands together until dry.
Other information ·Store at 20°C (68° to 77°F). · May discolor fabrics.
Inactive Ingredients ·Water (Aqua), Carbomer, Triethanolamine, Glycerin, Fragrance, Aloe Barbadensis Leaf Extract (Aloe Vera).
8 14266 02409 6
DISTRIBUTED IN USA AND CANADA BY:
4e Brands Northamerica, LLC. 17806 IH-10W Suite 300, San Antonio, Texas, 78257. Made in Mexico
4051443 /1047696


L 20:30 05:20 EXP 22/04/23


blumen
Clear
ADVANCED
HAND
SANITIZER
with 70% ALCOHOL
EXTRA SOFT
with GLYCERIN & ALOE
FREE

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	28-Jul-2020	CTU Received Date	28-Jul-2020
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Date the problem occurred	29-Apr-2020
Serious	Yes
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident(Please Describe Below)
Other serious/important medical incident(Please Describe Below)	Blurred vision

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

I applied the product to my hands and it left a sticky sensation. Soon after, I started to feel dizziness in my head and when walking I would lose balance somewhat. It started to affect my eyes in the form of itchiness and darkening of my vision.

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date	
Test Result		Test Unit	

Low Test Range		High Test Range		
More Information Available?				

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	Yes
Do you have a picture of the product? (check yes if you are including a picture)	Yes

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	Drug/Biologic		
This report is about	Drug		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Clear Advanced hand sanititzer		
Name of the company that makes (or compounds) the product	Blumen		
Product Type(check all that apply)	☐ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☑ Generic ☐ Biosimilar		
Strength		If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes		
Did the problem return if the person started taking or using the product again?	Doesn't Apply		

Drug Therapy 1 of 1

Expiration date	04-Apr-2023		
Lot number			
Dosage Form			
Quantity		If Other	
Frequency	Twice a day	If Other	
How was it taken or used	Topical	If Other	
Date the person first started taking or using the product	21-Apr-2020		

Date the person stopped taking or using the product	27-Jul-2020
Give best estimate of duration	
Is therapy still on-going?	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Protection against the covid-19 virus.

Returned to Manufacturer On	

Section D - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	

Section E - About the Person Who Had the Problem

Person's Initials	(b) (6)
Gender	Female
Age (specify unit of time for age)	82 Year(s)
Date of Birth	
Weight	
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaskan Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☐ White ☑ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

High Blood Pressure

Please list all allergies (such as to drugs, foods, pollen or others)

N/A

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

N/A

List all current prescription medications and medical devices being used.

High Blood Pressure Pills

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Stent

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	

	Department		
	Reporter Speciality		
	Today's date	28-Jul-2020	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

blumen
Clear
ADVANCED
HAND
SANITIZER
with 70% ALCOHOL
EXTRA SOFT
KILLS UP TO 99.9% OF GERMS
PARABENS & TRICLOSAN FREE
17 fl oz / 503 ml

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	29-Jul-2020	CTU Received Date	29-Jul-2020
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

	What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
	Date the problem occurred	18-Apr-2020
	Serious	Yes
	Did any of the following happen? (Check all that apply)	☑ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident(Please Describe Below)
	Other serious/important medical incident(Please Describe Below)	

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

Nausea, vomiting, diarrhea, blurred vision, weakness, dizziness, abdominal discomfort, heart racing, trouble breathing, loss of appetite, weight loss.

Relevant Test/Laboratory Data 1 of 7

Test Name	URINE SAMPLE TESTING	Test Date	(b) (6)	
Test Result	Negative for pregnancy and UTI	Test Unit		

Low Test Range		High Test Range		
More Information Available?				

Relevant Test/Laboratory Data 2 of 7

Test Name	COVID-19 TESTING	Test Date	(b) (6)
Test Result	Negative	Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Relevant Test/Laboratory Data 3 of 7

Test Name	LABORATORY TESTING	Test Date	(b) (6)
Test Result	Blood work negative	Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Relevant Test/Laboratory Data 4 of 7

Test Name	LABORATORY TESTING	Test Date	(b) (6)
Test Result	Blood work negative, Lyme negative	Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Relevant Test/Laboratory Data 5 of 7

Test Name	CT SCAN OF ABDOMEN	Test Date	(b) (6)
Test Result	Negative	Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Relevant Test/Laboratory Data 6 of 7

Test Name	STOOL SAMPLE TESTING	Test Date	(b) (6)
Test Result	Negative for parasites	Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Relevant Test/Laboratory Data 7 of 7

Test Name	STOOL SAMPLE TESTING	Test Date	(b) (6)
Test Result	Negative	Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	No
Do you have a picture of the product? (check yes if you are including a picture)	Yes

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	Drug/Biologic		
This report is about			
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Bluemen Hand Sanitizer		
Name of the company that makes (or compounds) the product			
Product Type(check all that apply)	☐ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
Strength		If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes		
Did the problem return if the person started taking or using the product again?	Doesn't Apply		

Drug Therapy 1 of 1

Expiration date			
Lot number			
Dosage Form			
Quantity		If Other	
Frequency		If Other	
How was it taken or used	Topical	If Other	
Date the person first started taking or using the product	06-Apr-2020		
Date the person stopped taking or using the product	02-Jul-2020		
Give best estimate of duration			
Is therapy still on-going?			

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Sanitization at work due to COVID-19

Returned to Manufacturer On	

Section D - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	

Section E - About the Person Who Had the Problem

Person's Initials	(b) (6)
Gender	Female
Age (specify unit of time for age)	27 Year(s)
Date of Birth	
Weight	70.2 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaskan Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

None

Please list all allergies (such as to drugs, foods, pollen or others)

None

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

None

List all current prescription medications and medical devices being used.

Junel FE birth control

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

None

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	

	Today's date	29-Jul-2020	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	


blumen
ADVANCED
HAND
SANITIZER
70% ALCOHOL CONTENT
EXTRA SOFT
FREE
blumen
ADVANCED
HAND
SANITIZER
FREE


blumen
ADVANCED
HAND
SANITIZER
70% ALCOHOL CONTENT
EXTRA SOFT
FREE
blumen
ADVANCED
HAND
SANITIZER
FREE

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	31-Jul-2020	CTU Received Date	31-Jul-2020
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Date the problem occurred	29-May-2020
Serious	Yes
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☑ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident(Please Describe Below)

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

I started using Blumen Advanced Hand sanitizer about 2 months ago and I started experiencing blurred vision and headaches. I have stopped using the product for the last 2-3 weeks, but the symptoms are still present.

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date	
Test Result		Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	Yes
Do you have a picture of the product? (check yes if you are including a picture)	No

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	Drug/Biologic		
This report is about	Drug		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Blumen Advanced Hand Sanitizer/ 70% ethyl alcohol		
Name of the company that makes (or compounds) the product	4E Global, SAPI de CV (Mexico)		
Product Type(check all that apply)	☑ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
Strength		If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?	No		
Did the problem return if the person started taking or using the product again?	Doesn't Apply		

Drug Therapy 1 of 1

Expiration date	13-Mar-2023		
Lot number	02362-4		
Dosage Form			
Quantity	Other	If Other	1 Application
Frequency	4 times a day	If Other	
How was it taken or used	Topical	If Other	
Date the person first started taking or using the product			
Date the person stopped taking or using the product			
Give best estimate of duration	2 Month		

Is therapy still on-going?	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Hand Sanitizer

Returned to Manufacturer On	

Section D - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	

Section E - About the Person Who Had the Problem

Person's Initials	(b) (6)
Gender	Female
Age (specify unit of time for age)	72 Year(s)
Date of Birth	
Weight	139 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaskan Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☐ White ☑ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

High blood pressure, diabetes, High Cholesterol, anxiety

Please list all allergies (such as to drugs, foods, pollen or others)

Pollen allergies

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

N/A

List all current prescription medications and medical devices being used.

Aspirin 325 mg as needed, atorvastatin, clonidine, lisinopril, bentyl as needed for abdominal pain, alprazolam

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Vitamin D 1000 units, Flonase

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	

	Today's date	31-Jul-2020	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	05-Aug-2020	CTU Received Date	05-Aug-2020
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Date the problem occurred	30-Apr-2020
Serious	Yes
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident(Please Describe Below)
Other serious/important medical incident(Please Describe Below)	Having vision problems and n

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

Me and my family have been using blumen hand sanitizer that we bought from (b) (6) early april and ive been noticing a problem ive been having with my vision and constantly getting nausea and im wortied because i have 4 kids and im not sure what it may have dont to them i have 2 kids with autism and im just not sure what this product has done to us

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date	
Test Result		Test Unit	

Low Test Range		High Test Range		
More Information Available?				

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	Yes
Do you have a picture of the product? (check yes if you are including a picture)	Yes

Section C - About the Products 1 of 1

Suspect	Yes			
Primary?	Yes			
Type	Drug/Biologic			
This report is about	Cosmetic,Dietary Supplement or Food/Medicinal Food			
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Blumen clear hand sanitizer			
Name of the company that makes (or compounds) the product				
Product Type(check all that apply)	☑ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar			
Strength		If Other		
NDC number				
Did the problem stop after the person reduced the dose or stopped taking or using the product?				
Did the problem return if the person started taking or using the product again?				

Drug Therapy 1 of 1

Expiration date				
Lot number				
Dosage Form				
Quantity		If Other		
Frequency		If Other		
How was it taken or used		If Other		
Date the person first started taking or using the product				

Date the person stopped taking or using the product	
Give best estimate of duration	
Is therapy still on-going?	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Returned to Manufacturer On	

Section D - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	

Section E - About the Person Who Had the Problem

Person's Initials	(b) (6)
Gender	Male
Age (specify unit of time for age)	24 Year(s)
Date of Birth	
Weight	
Ethnicity (Choose only one)	
Race (Check all that apply)	☐ American Indian or Alaskan Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☐ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Please list all allergies (such as to drugs, foods, pollen or others)

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	

	Department		
	Reporter Speciality		
	Today's date	05-Aug-2020	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

blumen
Clean
ADVANCED
HAND
SANITIZER
70%
ALCOHOL
EXTRA SOFT
FREE
17 fl oz / 503 ml

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	05-Aug-2020	CTU Received Date	05-Aug-2020
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Date the problem occurred	01-May-2020
Serious	Yes
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☑ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident(Please Describe Below)

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

Started using Blume hand sanitizer in May. Kept it in my car to use when running errands. I used approximately 8 oz over a 2 month period. I started feeling bad, brain fog, fatigue, headaches, blurred vision. Saw my doctor on jun 29 because of these symptoms. Found out the following week that the side effects from the hand sanitizer were the same as what I had been experiencing. Stopped use of sanitizer and problems went away.

Relevant Test/Laboratory Data 1 of 1

Test Name	FATIGUE & DIZZINESS	Test Date	29-Jun-2020
Test Result	Positive	Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	No
Do you have a picture of the product? (check yes if you are including a picture)	Yes

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	Drug/Biologic		
This report is about	Cosmetic,Dietary Supplement or Food/Medicinal Food		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Blumen Hand Sanitizer		
Name of the company that makes (or compounds) the product	4E Brands		
Product Type(check all that apply)	☑ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
Strength		If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes		
Did the problem return if the person started taking or using the product again?	Doesn't Apply		

Drug Therapy 1 of 1

Expiration date	04-Jul-2023		
Lot number	2261		
Dosage Form			
Quantity	Other	If Other	8 Ounce(s)
Frequency	As needed	If Other	
How was it taken or used	Topical	If Other	
Date the person first started taking or using the product	01-May-2020		
Date the person stopped taking or using the product	09-Jul-2020		
Give best estimate of duration			

Is therapy still on-going?	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Sanitize hands when running errands

Returned to Manufacturer On	

Section D - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	

Section E - About the Person Who Had the Problem

Person's Initials	(b) (6)
Gender	Female
Age (specify unit of time for age)	44 Year(s)
Date of Birth	
Weight	60.3 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaskan Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

None

Please list all allergies (such as to drugs, foods, pollen or others)

None

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

None

List all current prescription medications and medical devices being used.

None

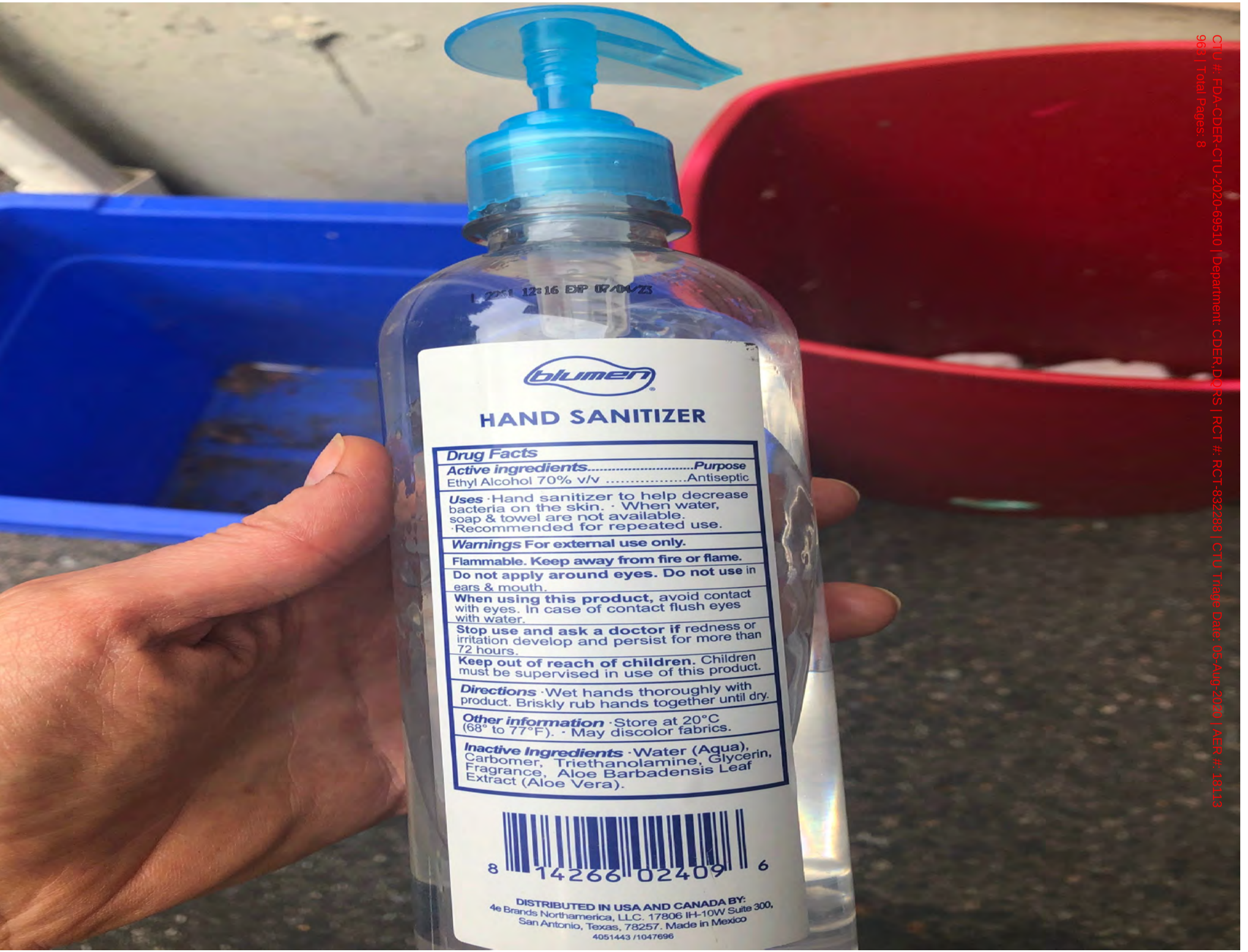
List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Olly multivitamins, collagen capsules, Zyrtec, viviscal, probiotic

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	

	Today's date	05-Aug-2020	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	



HAND
SANITIZER
KILLS UP TO 99.9% OF GERMS
PARABENS & TRICLOSAN FREE

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	05-Aug-2020	CTU Received Date	05-Aug-2020
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Date the problem occurred	25-May-2020
Serious	Yes
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☑ Disability or health problem ☐ Birth defect ☑ Life-threatening ☐ Death ☑ Other serious/important medical incident(Please Describe Below)
Other serious/important medical incident(Please Describe Below)	Problem breathing, walking,

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

Beginning approximately May 25 I began using Blumen Hand Sanitizer and began to get extremely ill (Chest pain, difficulty breathing, coughing, vomiting, nausea, dizziness, severe headache, confusion, blurred vision, drooling, unbalanced walking, tremors and shaking, diarrhea, loss of appetite, extreme pain in stomach and lower intestinal area, brown urine, bluish colored fingernails, white coated tongue, wheezing, tingling in arms and legs).I could hardly get out of my bed. Because I felt so sick I had a COVID 19 test done with the (b) (6) Health Department on (b) (6) which tested negative. As I still felt extremely sick my primary doctor office sent me for a second COVID test at the (b) (6) Hospital which also tested negative. So, twice I was checked for COVID19 and both times tested negative. Not until I received a recall notice in the mail on 7/24/20 from (b) (6) store did I realize there was a potential of methanol poisoning from the hand sanitizer I purchased from them. I did use the lot codes that were affected by the recall. I had used at least four 33.8 once size containers of this product as I did not know it could be harmful. Coincidentally I had also purchased and used two smaller sized containers of this same product from (b) (6) in (b) (6) .I immediately contacted my primary care physician office and explained what I just learned that could explain why I was so sick. I was told to immediately stop using the product and drink lots of water. I had to wait for an appointment however. I started a water fast to help my body purge toxins. After my doctor appointment on

7/27/20 I made appointments for a chest Xray and bloodwork. Unfortunately it seemed too much time had passed to determine methanol in the blood. I also had to wait to have blood test taken at (b) (6) because of all the Covid testing being done.

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date	
Test Result		Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	Yes
Do you have a picture of the product? (check yes if you are including a picture)	No

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	Drug/Biologic		
This report is about	Drug		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Blumen Clear Advanced Hand Sanitizer Antiseptic, 70% Alcohol		
Name of the company that makes (or compounds) the product	4e Brands NorthAmerica, LLC Distri		
Product Type(check all that apply)	☑ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
Strength	70% Ethyl Alcohol v/v % percent	If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?			
Did the problem return if the person started taking or using the product again?	Doesn't Apply		

Drug Therapy 1 of 1

Expiration date	28-Apr-2023
Lot number	2372

Dosage Form				
Quantity		If Other		
Frequency	As needed	If Other		
How was it taken or used	Topical	If Other		
Date the person first started taking or using the product	25-May-2020			
Date the person stopped taking or using the product	24-Jul-2020			
Give best estimate of duration				
Is therapy still on-going?				

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Result of COVID

Returned to Manufacturer On	

Section D - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	

Section E - About the Person Who Had the Problem

Person's Initials	(b) (6)
Gender	Female
Age (specify unit of time for age)	66 Year(s)
Date of Birth	
Weight	85.5 kg
Ethnicity (Choose only one)	Not Hispanic/Latino

Race (Check all that apply)	☐ American Indian or Alaskan Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Glaucome, Celiac

Please list all allergies (such as to drugs, foods, pollen or others)

Penicillin, Sulpher Drugs, Gluten

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

Latanoprost eye drops

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Multi VitaminMineral, Calcium with D3, melatonin, Vitamin C

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)

	Telephone number	(b) (6)	
	Email address	(b) (6)	
	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	05-Aug-2020	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	06-Aug-2020	CTU Received Date	06-Aug-2020
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Date the problem occurred	30-Mar-2020
Serious	Yes
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident(Please Describe Below)
Other serious/important medical incident(Please Describe Below)	Hands Burning and Swallon

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

I am sending you the email that I sent the company, after contacting them in few occassions and not hearing from them. Dear Company: I just want to inform you that I received the letter dated on the 14th of July (which I received on the 29th of July from (b) (6) in regards of the contamination with Methyl alcohol in the bottle of Blumen sanitazer product I bought. As soon as I received it I spoke to (b) (6) on the 29th of July and Explained to her the terrible situation I went through and she gave me the reference number that I wrote in the top of my message. That I had to go to the Emergency room because my hands were burning badly. I didn´t understand why this happened to me, but once I received the letter last week, I realized. She told me that within the next day or so I will receive a phone call. I still have the bottle of the hand sanitazer and the bill from the Emergency room. It took me about 2 weeks to recuparate since the feeling was terrible of burning and it was swalloging badly even 4 days before going to the Emergency room. I waited until today (the 4th of August) for someone to call me, and to my surprise, nobody called me to give me a solution to this issue, and that is at least what the company should of done. I decided that I am not waiting any longer and called 4E. I spoke to (b) (6) and she said that all the Managers were very busy but that someone will give me a call, (like (b) (6) she was very nice understanding the situation, however I waited for a long time and finally I was able to speak to (b) (6) She explained to me that she doesn´t know whe then Medical Department will call

me but that they have a high volume of enquieries. I understand that a lots of people will want the money back but I had a very urgent issue but I should of been contacted before, since this was a priority for the seriousness of my burning. I please ask someone to get in contact with me, to seek further action. Yours sincerely, (b) (6)

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date	30-Mar-2020
Test Result		Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Additional Comments

I beleived at that time that I had a reaction of some hand gloves however after I received the first letter from (b) (6) Recall, I realized that it was the hand sanitazer (even do I told the Emergency Doctor at that point that I thought it was the gloves. As the doctor stated in the Emergency Room Report, the Final Diagnosis was Allergic Reaction and the Additional Diagnosis was contact dermatitis Bilateral hands. The Medication they gave me was Benadryl Dose 50 milligrams Intramscular, because I had so much pain and my hands were burning. The prescriptions were 2: Benadryl Capsule 25mg Oral Hydrocortisone Topical ointment 1% topical.

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	Yes
Do you have a picture of the product? (check yes if you are including a picture)	Yes

Section C - About the Products 1 of 1

Suspect	Yes
Primary?	Yes
Type	Drug/Biologic
This report is about	
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Blumen Clear Hand Sanitizer
Name of the company that makes (or compounds) the product	4E Brands
Product Type(check all that apply)	☑ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar
Strength	If Other
NDC number	814266024096
Did the problem stop after the person reduced the dose or stopped taking or using the product?	No
Did the problem return if the person started taking or using the product again?	Doesn't Apply

Drug Therapy 1 of 1

Expiration date	29-May-2023

Lot number	3949			
Dosage Form				
Quantity		If Other		
Frequency		If Other		
How was it taken or used	Topical	If Other		
Date the person first started taking or using the product	29-Mar-2020			
Date the person stopped taking or using the product	30-Mar-2020			
Give best estimate of duration				
Is therapy still on-going?				

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Covid 19

Returned to Manufacturer On	

Section D - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	

Section E - About the Person Who Had the Problem

Person's Initials	(b) (6)
Gender	Female
Age (specify unit of time for age)	45 Year(s)
Date of Birth	
Weight	71.1 kg

Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaskan Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

None

Please list all allergies (such as to drugs, foods, pollen or others)

None

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

None

List all current prescription medications and medical devices being used.

None

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

None

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES

	ZIP or Postal code		
	Telephone number	(b) (6)	
	Email address	(b) (6)	
	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	06-Aug-2020	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

blumen
Clean
ADVANCED
HAND
SANITIZER
with 70% ALCOHOL
EXTRA SOFT
with GLYCERIN & ALOE
KILLS UP TO 99.9% OF GERMS
PARABENS & TRICLOSAN FREE
17 fl oz / 503 ml

blumen
Clear
ADVANCED
HAND
SANITIZER
with 70% ALCOHOL
EXTRA SOFT
FREE