CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-909

PROPRIETARY NAME REVIEW(S)

CONSULTATION RESPONSE
DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY
(DMETS; WO22, Mail Stop 4447)

DATE RECEIVED: November 29, 2006 **DOCUMENT DATE:** September 28, 2006	**DESIRED COMPLETION DATE:** May 25, 2007 **PDUFA DATE:** July 27, 2007	**OSE REVIEW #:** 2006-913

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PRODUCT NAME: **Allegra ODT**
(Fexofenadine Hydrochloride) Orally Disintegrating Tablets
30 mg

NDA #: 21-909

NDA SPONSOR: Sanofi-Aventis, U.S., LLC

RECOMMENDATIONS:

1. DMETS has no objections to the use of the proprietary name, Allegra ODT. This is considered a tentative decision. This name must be re-evaluated approximately 90 days prior to the expected approval of the NDA. A re-review of the name will rule out any objections based upon approval of other proprietary or established names from the signature date of this document.

2. DMETS recommends implementation of the label and labeling revisions outlined in Section III of this review to minimize potential errors with the use of this product.

3. DDMAC has no objections to the proposed trade name, Allegra ODT, from a promotional perspective.

DMETS would appreciate feedback of the final outcome of this consult. We would be willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications, please contact Sammie Beam, Project Manager, at 301-796-0080.

Division of Medication Errors and Technical Support (DMETS)
Office of Surveillance and Epidemiology
White Oak 22, Mail Stop 4447
Center for Drug Evaluation and Research

PROPRIETARY NAME, LABEL, AND LABELING REVIEW

DATE OF REVIEW: January 22, 2007

NDA# 21-909

NAME OF DRUG: **Allegra ODT**
(Fexofenadine Hydrochloride)
Orally Disintegrating Tablets
30 mg

NDA HOLDER: Sanofi-Aventis, U.S., LLC

I. INTRODUCTION:

This consult was written in response to a request from the Division of Pulmonary and Allergy Products, for assessment of the proprietary name, Allegra ODT, regarding potential name confusion with other proprietary and/or established drug names. Allegra ODT is a new dosage form for the Allegra product line. The existing product line of Allegra is described in the chart below. Container labels, carton, and insert labeling for this new dosage form, Allegra ODT, were provided for review and comment.

Proprietary Name	Active Ingredient(s), Dosage Form, and Strength	NDA Number	Approval Date
Allegra	Fexofenadine HCl Capsules: 60 mg *(no longer marketed)*	NDA 20-625	July 25, 1996
Allegra-D 12 Hour	Fexofenadine HCl/Pseudoephedrine HCl Extended-release Tablets: 60 mg/120 mg	NDA 20-786	December 24, 1997
Allegra	Fexofenadine HCl Tablets: 30 mg, 60 mg, 180 mg	NDA 20-872	February 25, 2000
Allegra D 24 Hour	Fexofenadine HCl/Pseudoephedrine HCl: Extended-release Tablets: 180 mg/240 mg	NDA 21-704	October 19, 2004
Allegra Oral Suspension	Fexofenadine HCl Oral Suspension: 30 mg/5 mL	NDA 21-963	October 16, 2006

PRODUCT INFORMATION

Allegra ODT is the proposed proprietary name for a new dosage form in the Allegra product line, an orally disintegrating tablet formulation of Fexofenadine Hydrochloride. Allegra ODT is proposed to be available by prescription. The proposed indication of Allegra ODT is for seasonal allergic rhinitis and chronic idiopathic urticaria. Allegra ODT is intended for use only in children 6 to 11 years of age. The recommended dose of Allegra ODT is 30 mg twice daily. A dose of 30 mg once daily is recommended as the starting dose in pediatric patients with decreased renal function. The Sponsor states that Allegra ODT is designed to quickly disintegrate on the tongue, followed by swallowing with or without water. Allegra ODT should be taken on an empty stomach. DMETS notes the other Allegra products do not carry this recommendation. Allegra ODT is not intended to be chewed. Allegra ODT should be stored at controlled room temperature and should not be removed from the original blister package until the time of administration.

----------DOSAGE AND ADMINISTRATION----------

Patient Population	Dosage Regimens		
	ALLEGRA Tablets	ALLEGRA ODT	ALLEGRA Oral Suspension
Adults and children ≥ 12 years	60 mg twice daily[1, 2] or 180 mg once daily[2, 3]	N/A	N/A
Children 6 to 11 years	30 mg twice daily[1, 2]	30 mg twice daily[1, 4]	30 mg twice daily[1]
Children 2 to 5 years	N/A	N/A	30 mg twice daily[1]
Children 6 months to less than 2 years	N/A	N/A	15 mg twice daily[1, 5]

[1] starting dose in patients with decreased renal function should be the recommended dose indicated above but administered once daily
[2] with water
[3] dose not for use in patients with decreased renal function
[4] take on an empty stomach
[5] indicated for chronic idiopathic urticaria only

II. RISK ASSESSMENT:

The medication error staff of DMETS conducted a search of the internet, several standard published drug product reference texts[1,2] as well as several FDA databases[3,4] for existing drug names which sound-alike or look-alike to Allegra ODT to a degree where potential confusion between drug names could occur under the usual clinical practice settings. A search of the electronic online version of the U.S. Patent and Trademark Office's Text and Image Database was also conducted[5]. The Saegis[6] Pharma-In-Use database was searched for drug names with potential for confusion. An expert panel discussion was conducted to review all findings from the searches. In addition, DMETS conducted three prescription analysis studies consisting of two written prescription studies (inpatient and outpatient) and one verbal prescription study, involving health care practitioners within FDA. This exercise was conducted to simulate the prescription ordering process in order to evaluate potential errors in handwriting and verbal communication of the name. Following completion of these initial components, an overall risk assessment is conducted that does not evaluate the name alone. The assessment considers the findings from above and more importantly integrates post-marketing experience in assessing the risk of name confusion, product label/labeling, and product packaging. Because it is the product that is inserted into the complex and unpredictable U.S. healthcare environment, all product characteristics of a product must be considered in the overall safety evaluator risk assessment.

A. EXPERT PANEL DISCUSSION (EPD)

An Expert Panel discussion was held by DMETS to gather professional opinions on the safety of the proprietary name, Allegra ODT. Potential concerns regarding drug marketing and promotion related to the proposed names were also discussed. This group is composed of DMETS Medication Errors Prevention Staff and representation from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The group relies on their clinical

[1] MICROMEDEX Integrated Index, 2007, MICROMEDEX, Inc., 6200 South Syracuse Way, Suite 300, Englewood, Colorado 80111-4740, which includes all products/databases within ChemKnowledge, DrugKnowledge, and RegsKnowledge Systems.
[2] Facts and Comparisons, online version, Facts and Comparisons, St. Louis, MO.
[3] AMF Decision Support System [DSS], the Division of Medication Errors and Technical Support [DMETS] database of Proprietary name consultation requests, New Drug Approvals 98-07, and the electronic online version of the FDA Orange Book.
[4] Phonetic and Orthographic Computer Analysis (POCA)
[5] WWW location http://www.uspto.gov/tmdb/index.html.
[6] Data provided by Thomson & Thomson's SAEGIS ™ Online Service, available at www.thomson-thomson.com

and other professional experiences and a number of standard references when making a decision on the acceptability of a proprietary name.

1. DDMAC has no objections to the proposed trade name, Allegra ODT, from a promotional perspective

2. The Expert Panel identified the following concerns with the proposed proprietary name Allegra ODT.

   a. Two names were thought to have look-alike and/or sound-alike confusion with Allegra ODT. These are Alkeran and Albenza (see Table 1 below).
   b. The potential for confusion within the Allegra product line. Specifically, the panel was concerned that Allegra D could be confused with Allegra ODT (see Table 1 below).
   c. Five names were identified that shared the modifier "ODT" which could lead to potential confusion. These are Aricept ODT, Fazaclo ODT, OraPred ODT, Reglan ODT, and Zofran ODT.

Table 1: ALLEGRA ODT: Potential Sound-Alike/Look-Alike Names Identified by DMETS Expert Panel

Product Name	Dosage form(s); Established name	Usual adult dose	Other**
Allegra ODT	Fexofenadine Hydrochloride Orally Disintegrating Tablets: 30 mg	Children 6-11 years: One tablet (30 mg) twice daily Dose for decreased renal function is 30 mg once daily.	N/A
Allegra Suspension	Fexofenadine Hydrochloride Suspension, Oral: 30 mg/ 5 mL	Children under 12 years: SAR: 30 mg by mouth twice daily. Dose for decreased renal function is 30 mg once daily. CIU: 15 mg by mouth twice daily for children ≤ 10.5 kg and 30 mg twice daily for children > 10.5 kg and ≥ 6 months of age. Dose for decreased renal function is usual dose once daily.	LA/SA
Allegra	Fexofenadine Hydrochloride Tablets: 30 mg, 60 mg, 180 mg	Adults and adolescents ≥ 12 years: 60 mg twice daily or 180 mg once daily. Children 6-11 years: 30 mg twice daily.	LA/SA
Allegra-D (renamed) Allegra-D 12 Hour	Fexofenadine HCl and Pseudoephedrine HCl Extended-Release Tablets: 60 mg/120 mg (12 Hr)	One tablet twice daily	LA/SA
Allegra D 24 Hour	Fexofenadine HCl and Pseudoephedrine HCl Extended-Release Tablets: 120 mg/240 mg (24 Hr)	One tablet once daily	LA/SA
Albenza	Albendazole Tablets: 200 mg	Adults ≥ 60 kg: 400 mg orally twice daily with meals for 28 days followed by a 14-day drug-free period. Repeat for 2 to 5 more cycles. Adults < 60 kg: 15 mg/kg/day (not to exceed 800 mg/day) given in two divided doses for 28 days followed by a 14-day drug-free period. Repeat as above.	LA

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Product Name	Dosage form(s), Established name	Usual adult dose*	Other**
Allegra ODT	Fexofenadine Hydrochloride Orally Disintegrating Tablets: 30 mg	Children 6-11 years: One tablet (30 mg) twice daily. Dose for decreased renal function is 30 mg once daily.	N/A
Alkeran	Melphalan Tablets: 2 mg Powder for Injection: 50 mg	For the treatment of multiple myeloma:	LA

*Frequently used, not all-inclusive.
**L/A (look-alike), S/A (sound-alike)

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B. PRESCRIPTION ANALYSIS STUDIES

1. Methodology:

Three separate studies were conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of Allegra ODT with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. These studies employed a total of 124 health care professionals (pharmacists, physicians, and nurses). This exercise was conducted in an attempt to simulate the ordering process. Two prescription orders were written, each consisting of a combination of marketed and unapproved drug products and an order for Allegra ODT (see below) were written. These orders were optically scanned and one order was delivered to a random sample of the participating health professionals via e-mail. In addition, a verbal order was recorded on voice mail. The voice mail messages were then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal orders, the participants sent their interpretations of the orders via e-mail to the medication error staff.

HANDWRITTEN ORDER	VERBAL ORDER
Inpatient Prescription: Allegra ODT 1 tab daily	"Allegra ODT, Quantity of 30, Take one tablet daily."
Outpatient Prescription: Allegra ODT #30 1 tablet daily	

2. Results for Allegra ODT:

Two respondents from the inpatient study, one respondent from the outpatient study, and one respondent from the verbal study interpreted the proposed name as "Allegra" rather than "Allegra ODT." Additionally, two respondents from the verbal study interpreted the proposed name as "Allegra OD" rather than "Allegra ODT". DMETS notes that "OD" is a commonly used abbreviation for "right eye". However, as there is no ophthalmic dosage form of Allegra, it is unlikely that this abbreviation could be misinterpreted resulting in the administration of Allegra into the right eye. The remaining misinterpretations were misspelled/phonetic variations of the name, Allegra ODT. See Appendix A for the complete listing of interpretations from the verbal and written studies.

C. ADVERSE EVENT REPORTING SYSTEM (AERS)

DMETS conducted a search of the Adverse Event Reporting System (AERS) for medication errors associated with the Allegra product line. A similar search was performed in August of 2005 in OSE Consult # 05-0179 for the review of the name "Allegra Suspension". Therefore an updated AERS search was conducted for the dates of January 1, 2005 to January 25, 2007 to identify any additional cases concerning the Allegra product line reported since that time. The preferred terms "overdose", "accidental overdose", "pharmaceutical product complaint", "treatment noncompliance", "medication error", "underdose", "accidental exposure", "intercepted medication error", "circumstance or information capable of leading to medication error", "drug prescribing error", and "drug dispensing error" were used. The higher level terms "medication errors due to accidental exposures" and "maladministrations" were used. DMETS has not identified any new reports since January 1, 2005 of post-market confusion with the nomenclature, label, and labeling of the Allegra product line. Since Alkeran, Albenza, and the Allegra product line were identified as having potential look-alike or sound-alike confusion with Allegra ODT, DMETS searched AERS with the same terms. No cases of confusion were found between the names Allegra and either Alkeran, Albenza, or other products in the Allegra product line.

D. SAFETY EVALUATOR RISK ASSESSMENT

1. Review of Look and Sound-alike Names

In reviewing the proprietary name Allegra ODT, the names identified as having the potential for look-alike and sound-alike confusion with Allegra ODT are Alkeran, and Albenza. Additionally, the potential for confusion within the Allegra product line was identified, specifically confusion between Allegra D and Allegra ODT. Finally, confusion due to the shared modifier "ODT" of Aricept ODT, Fazaclo ODT, OraPred ODT, Reglan ODT, and Zofran ODT was noted.

DMETS conducted prescription studies to simulate the prescription ordering process. Two respondents from the inpatient study, one respondent from the outpatient study, and one respondent from the verbal study interpreted the proposed name as "Allegra" rather than "Allegra ODT." Additionally, two respondents from the verbal study interpreted the proposed name as "Allegra OD" rather than "Allegra ODT". DMETS notes that "OD" is a commonly used abbreviation for "right eye". However, as there is no ophthalmic dosage form of Allegra, it is unlikely that this abbreviation could be misinterpreted resulting in the administration of Allegra into the right eye. The remaining

misinterpretations were misspelled/phonetic variations of the name, Allegra ODT. See Appendix A for the complete listing of interpretations from the verbal and written studies.

Upon initial review of the aforementioned names, Albenza and Alkeran were not reviewed further due to a lack of convincing look-alike/sound-alike similarities with Allegra ODT, in addition to numerous differentiating product characteristics such as the indication for use, product strength, usual dose, route of administration, frequency of administration, prescribing population, patient population, dosage form, storage conditions, product unavailability and/or area of marketing or distribution. Furthermore, DMETS' search of the AERS database found no reports of confusion with the current Allegra product line and the aforementioned marketed names (Alkeran and Albenza).

Upon review of the names that share the ODT modifier we have the following comments: The names with the potential for confusion due to the shared modifier ODT, were not reviewed further because they are no longer available or lack sufficent cause for error. Reglan ODT has been discontinued; therefore the potential for confusion is no longer a concern. Aricept ODT, Fazaclo ODT, OraPred ODT, and Zofran ODT were not reviewed further as they lack a root name similar in sound or appearance to Allegra. Furthermore, these products have differentiating product characteristics which may include one or more of the following: indication for use, product strength, usual dose, frequency of administration, prescribing population, patient population, storage conditions, product unavailability and/or area of marketing or distribution.

The remaining concern is the potential for confusion within the Allegra product line because there will likely be a knowledge deficit among healthcare professionals concerning the existence of this new formulation and the similar appearance of the ODT suffix to existing Allergra suffixes. Although there is potential for confusion, it is still the preferred method for naming this product, If a suffix was not used then a new name would be required. This alternative is not recommended.

Allegra ODT is the latest product extension to the Allegra product line. Allegra is currently approved as a tablet and oral suspension. Additionally, there are also two extended-release tablet formulations of Allegra (Fexofenadine) co-formulated with Pseudoephedrine with the names Allegra-D 12 Hour and Allegra D 24 Hour. Since all the products share the root name (Allegra), confusion might occur between these products if the modifier was omitted. If the modifier for Allegra ODT is omitted, the patient would likely receive Allegra oral suspension (30 mg/5mL) or tablets (30 mg). Although both products contain the same ingredient, dose and frequency, the formulation may not be optimal for the patient's particular medical situation. The orally disintegrating tablet may be optimal for children who are unable or unwilling to take the tablet or suspension formulation of Allegra. However, it is likely that prescriptions for any of the three products (Allegra ODT, Allegra Tablets, and Allegra Oral Suspension) will contain additional directions for use and/or descriptors on the prescription (e.g., dissolve, milliliters, teaspoons, tablets, suspension, etc.) that may help to differentiate between the names and decrease the potential for confusion.

Additionally, the Expert Panel commented that Allegra ODT could be mistaken for Allegra D. If the modifier for Allegra ODT is interpreted as Allegra D, the patient could potentially receive one of the extended-release tablet formulations of fexofenadine/pseudoephedrine. However, a prescription for Allegra ODT interpreted as

"Allegra D" with or without a specified 30 mg strength would prompt a call to the prescriber to determine whether Allegra-D 12 hour or Allegra D 24 hour was intended as the 12 hour formulation contains 60 mg and the 24 hour formulation contains [redacted] of the Fexofenadine component. Furthermore, as the full modifier is "ODT", which consists of three letters when written or spoken, it appears unlikely that the interpretation will be for a single letter "D". Thus, DMETS believes the potential for confusion between Allegra ODT and Allegra D is low. b(4

Upon approval of this new dosage formulation of Allegra, it is imperative that healthcare practitioners are educated about the existence of this orally disintegrating tablet formulation and understand the differences between the products in the entire Allegra product line. Practitioners will need to further clarify which dosage form will be appropriate for the individual patient prior to dispensing the drug. It is essential that the product labels and labeling highlight the differences between the products to further reduce the potential for medication errors. DMETS recommends an extensive education campaign to alert health care practitioners to the new dosage forms including product differences.

2. Review of Modifier (ODT)

DMETS evaluated the modifier 'ODT' for possible confusion among healthcare professionals. Currently, there are a number of products that employ a modifier in the proprietary name to identify an orally disintegrating product (see Table 2 below). Although there is a theoretical potential for confusion among the modifiers of the currently marketed orally disintegrating tablets, we have not received any cases of confusion with these product names. The modifier 'ODT' has been used to convey "orally disintegrating tablet" and is recognized by healthcare providers for this meaning. Additionally, DMETS believes that it is unlikely that the root names of the drugs listed in Table 2 would be confused with the root name Allegra due to the different orthographic and phonologic presentation. However, upon approval of the product Allegra ODT, practitioners will still need to be educated with regards to the use of the appropriate modifier to decrease the potential for confusion with currently used modifiers and within the Allegra product line.

Table 2

Modifiers for Orally Disintegrating Tablets	
Product Name	**Modifier**
Maxalt MLT	MLT (Melt)
Zofran ODT	ODT (Orally Disintegrating Tablets)
Fazaclo ODT	Clozapine (Orally Disintegrating Tablets)
Aricept ODT	Donepezil Hydrochloride (Orally Disintegrating Tablets)
Reglan ODT	Metoclopramide Hydrochloride (Orally Disintegrating Tablets)
OraPred ODT	Prednisolone Sodium Phosphate (Orally Disintegrating Tablets)
[redacted]	[redacted]
Claritin Reditabs	Reditabs
Pepcid RPD	(RPD) No discernable meaning **
Remeron Soltab	Soltab
Zomig ZMT	(ZMT) No discernable meaning
Zyprexa Zydis	Zydis
* Proposed not FOI releasable. ** Per United States Patent and Trademark Office	

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III. LABELING, PACKAGING, AND SAFETY RELATED ISSUES

In the review of the container label, carton and insert labeling of Allegra ODT, DMETS has focused on safety issues relating to possible medication errors. DMETS has identified the following areas of improvement that may minimize potential user error.

A. CARTON LABELING (Carton containing ten 6-count blister cards)

1. DMETS recommends that the statement "Rx Only" appear on the principal display panel of the carton, rather than on the back panel where it can be overlooked by the reader.

2. The net quantity for each carton should be revised to read "Contains Ten Blister Cards each containing Six Tablets", or something similar so as to clearly identify the contents. Revise accordingly.

3. The dosage form "Orally Disintegrating Tablets" should be enlarged and relocated to immediately follow the established name "fexofenadine HCl". If this text is moved as recommended, please make sure the product strength and net quantity remain separated.

4. The text "mg" in "30 mg" should be in the same font/bold status as the text "30". Additionally, a space should be inserted between the "30" and the "mg".

5. Add the statement "Do not break or use partial ODT tablets" to all labeling. Additionally, relocate the recommendation to keep Allegra ODT in the original blister package until the time of administration higher up on the back panel as a stand alone sentence, under Dosage and Administration to decrease the possibility that the reader will overlook this recommendation. As currently displayed, this information is buried in the storage recommendations on the back panel.

6. Ensure that the labels and labeling for Allegra ODT are distinct from Allegra and Allegra-D to decrease the potential for selection errors.

B. BLISTER LABELS (6-count blister card)

1. The text "Orally Disintegrating Tablets" should be enlarged and relocated to immediately follow the established name "fexofenadine HCl". If this text is moved as recommended, please make sure the product strength and net quantity remain separated.

2. The text "mg" in "30 mg" should be in the same font/bold status as the text "30". Additionally, a space should be inserted between the "30" and the "mg".

3. Add the statement "Do not break or use partial ODT tablets" to all labels and labeling if space permits.

4. If space permits, move the recommendation to keep Allegra ODT in the original blister package until the time of administration higher up on the back panel as a stand alone sentence, under Dosage and Administration to decrease the possibility that the reader will overlook this recommendation. As currently displayed, this information is buried in the storage recommendations on the back panel.

5. Ensure that the labels and labeling for Allegra ODT are distinct from Allegra and Allegra-D to decrease the potential for selection errors.

C. PACKAGE INSERT LABELING (new format)

1. HIGHLIGHTS OF PRESCRIBING INFORMATION
DOSAGE AND ADMINISTRATION section

DMETS recommends that additional important information on the use of Allegra ODT be included in the chart as footnotes, such as; 1) Allegra ODT should be allowed to disintegrate on the tongue and then swallowed with or without water, and, 2) Allegra ODT should not be removed from the original blister package until the time of administration, and 3) Do not break or use partial ODT tablets.

2. HIGHLIGHTS OF PRESCRIBING INFORMATION
WARNINGS AND PRECAUTIONS section

DMETS recommends that a statement be included such as "[redacted]

3. FULL PRESCRIBING INFORMATION
WARNINGS AND PRECAUTIONS section

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DMETS recommends that a statement be included such as '[redacted] under Section 5. As currently written, the full prescribing information lacks a Section 5.

4. FULL PRESCRIBING INFORMATION
Special Populations, *Renally Impaired* section

DMETS requests clarification of the parameters of renal impairment in pediatric patients. The package insert labeling states that the starting dose in patients with decreased renal function should be the recommended dose but administered once daily. However, the Special Populations, Renally Impaired section appears to only provides parameters of renal impairment based on creatinine clearance [e.g., mild to moderate (creatinine clearance 41-80 mL/min) and severe (11-40 mL/min)] in adults. The package insert does not state the parameters of renal impairment that should be used to determine if a pediatric patient has renal impairment. DMETS recommends that [redacted] b(4 b(5

Appendix A: Allegra ODT

Inpatient	Voice	Outpatient
Allegra ODT	Allergra ODT	Allegra ODT
Allegra ODT	ALLEGRA ODT	Allegra OD
Allegra ODT	Allegra ODT	Allegra ODT
Allegra ODT	Allegra ODT	Allegra
Allegra	Allegra ODT	Allegra ODT
Allegra ODT	Allegra ODT	Allegra ODT
Allegra ODT	Allegra	Allegra OD
Allegra ODT	Allegra ODT	Allegra ODT
Allegra ODT	Allegra ODT	Allegra ODT
Allegra ODT	Allegra ODT	
Allegra	Alegra ODT	
Allegra ODT	Allegra ODT	
Allegra ODT	Allegra ODT	
	Allegra ODT	

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